

**U.S. DEPARTMENT OF HEALTH AND HUMAN SERVICES  
CENTERS FOR DISEASE CONTROL AND PREVENTION  
HEALTH RESOURCES AND SERVICES ADMINISTRATION**



**Meeting of the CDC/HRSA Advisory Committee on HIV,  
Viral Hepatitis and STD Prevention and Treatment  
June 18-19, 2013  
Atlanta, Georgia**

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**DRAFT Record of the Proceedings**

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**CDC/HRSA ADVISORY COMMITTEE ON HIV,  
VIRAL HEPATITIS AND STD PREVENTION AND TREATMENT  
June 18-19, 2013  
Atlanta, Georgia**

**DRAFT Minutes of the Meeting**

The U.S. Department of Health and Human Services (HHS), the Centers for Disease Control and Prevention (CDC) National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention (NCHHSTP), and the Health Resources and Services Administration (HRSA) HIV/AIDS Bureau (HAB) convened a meeting of the CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment (CHAC). The proceedings were held on June 18-19, 2013 in Building 8 of CDC's Corporate Square Campus, Conference Room A/B/C, in Atlanta, Georgia.

CHAC is chartered to advise the Secretary of HHS, Director of CDC, and Administrator of HRSA on objectives, strategies, policies and priorities for HIV, viral hepatitis and STD prevention and treatment efforts for the nation.

**Opening Session: June 18, 2013**

**John Douglas, Jr., MD**

Chief Medical Officer, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention  
CHAC Designated Federal Officer, CDC

Dr. Douglas conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representatives who were in attendance. He asked the voting members to publicly disclose their individual and/or institutional conflicts of interest for the record.

- Bruce Agins, MD, MPH: Recipient of federal funding from CDC and HRSA; recipient of HRSA-funded quality management grants
- Sanjeev Arora, MD, FACP: Recipient of federal funding from CDC, the Agency for Healthcare Research and Quality, and the Center for Medicare and Medicaid Innovation (CMMI); recipient of funding from multiple pharmaceutical companies for the development of new hepatitis C virus (HCV) drugs in clinical trials
- Virginia Caine, MD: Recipient of federal funding from CDC for surveillance and disease investigation services (DIS); recipient of federal Ryan White funding from HRSA; member of the National Medical Association Advisory Committee for Hepatitis C
- Guillermo Chacon: Recipient of federal funding from CDC, the Office of Minority Health, and National Institutes of Health (NIH); recipient of funding from multiple pharmaceutical companies for awareness, education and treatment initiatives
- Kathleen Clanon, MD: Recipient of federal grant support from HRSA
- Angelique Croasdale, MA: Recipient of federal funding from CDC and HRSA
- Carlos del Rio, MD: Recipient of federal funding from CDC and NIH; care provider in a HRSA-funded Ryan White clinic; advisor to Pfizer
- Dawn Fukuda, ScM: Recipient of federal CDC funding and Ryan White funding from HRSA
- Perry Halkitis, PhD, MS: Recipient of federal funding from NIH; board member of the American Psychological Association
- Steven Johnson, MD: Recipient of federal Ryan White funding from HRSA; consultant to Gilead and Viva Pharmaceutical
- Kali Lindsey: Recipient of federal CDC funding
- Jeanne Marrazzo, MD, MPH: Recipient of federal CDC funding for an STD Prevention Training Center (PTC) and a hepatitis educational website; care provider in a HRSA-funded Ryan White clinic

Dr. Douglas announced that the voting members and *ex-officio* members constituted a quorum for CHAC to conduct its business on June 18, 2013. He called the proceedings to order at 8:36 a.m. and welcomed the participants to day 1 of the CHAC meeting.

Dr. Douglas announced that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded the CHAC voting members of their individual responsibility to identify real or perceived conflicts of interest and recuse themselves from participating in these matters.

Dr. Douglas noted that biographical sketches of four new CDC-appointed CHAC members were included in the meeting packets. He asked the participants to join him in welcoming the new members:

- Sanjeev Arora, MD, FACP: Professor, Department of Internal Medicine, University of New Mexico Health Sciences Center

- Virginia Caine, MD: Director, Marion County (Indianapolis) Public Health Department
- Guillermo Chacon: President, Latino Commission on AIDS
- Dawn Fukuda, ScM: Director, Office of HIV/AIDS, Massachusetts Department of Public Health

Dr. Douglas announced that Dr. Gretchen Stiers recently accepted a position with another federal agency and is no longer serving as the CHAC *ex-officio* member for the Substance Abuse and Mental Health Services Administration (SAMHSA). Efforts are underway to fill this vacancy before the next CHAC meeting.

**Jeanne Marrazzo, MD, MPH, CHAC co-Chair**  
 Professor of Medicine, Harborview Medical Center  
 University of Washington

**Antigone Dempsey MEd, CHAC co-Chair**  
 Deputy Director, Knowledge, Transfer and Technical Assistance  
 HIV/AIDS Lead, Altarum Institute

**Laura Cheever, MD, ScM**  
 (Acting) Associate Administrator and Chief Medical Officer, HIV/AIDS Bureau  
 Health Resources and Services Administration  
 CHAC Designated Federal Official, HRSA

Dr. Marrazzo, Ms. Dempsey and Dr. Cheever joined Dr. Douglas in welcoming the participants to the 20<sup>th</sup> CHAC meeting. The members were thanked for continuing to commit their valuable time to attend CHAC meetings and provide HHS, CDC and HRSA with excellent guidance on HIV, viral hepatitis and STD prevention and treatment for the nation.

The four new members were thanked for enriching CHAC's advisory role by contributing their outstanding expertise from public health, academic and national organization perspectives. The members of the public also were thanked for continuing to attend meetings to provide CHAC with thoughtful insights and helpful stakeholder input from the field. Ms. Dempsey concluded the opening session by reviewing the agenda for the June 18-19, 2013 CHAC meeting.

### CDC/NCHHSTP Director's Report

**Rima Khabbaz, MD**  
 Deputy Director, CDC Office of Infectious Diseases  
 (Acting) Director, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
 Centers for Disease Control and Prevention

Dr. Khabbaz covered the following topics in her Director's report to CHAC. At the agency level, several changes have occurred in CDC's leadership since the December 2012 CHAC meeting. Dr. Thomas Kenyon is the new Director of the Center for Global Health. Dr. Kathleen Ethier is the Acting Associate Director for Program. Mr. Charles Rothwell is the Acting Director of the National Center for Health Statistics. Dr. Robin Ikeda is the Acting Director of the National Center for Environmental Health/Agency for Toxic Substances and Disease Registry.

CDC published a *Vital Signs* Report in May 2013, "Hepatitis C: Testing Baby Boomers Saves Lives," that was based on HCV testing outcomes from 8 active surveillance sites. The report noted that "baby boomers" (*i.e.*, persons born in 1945-1965) account for the majority of ~3 million adults in the United States who are infected with HCV. In this population, up to 3 out of 4 HCV-infected persons have no knowledge of their status. The report emphasized the need for baby boomers to get tested for HCV testing.

In terms of the CDC FY2013 budget, Congress authorized a continuing resolution that includes cuts due to sequestration. As a result, all of CDC's budget line items decreased by 5%. The FY2014 budget request is based on the FY2012 budget. CDC's FY2014 budget request of \$6.6 billion accounts for the Affordable Care Act (ACA), Prevention and Public Health Fund (PPHF) and U.S. Public Health Service evaluation funds, but the request is \$270 million below the FY2012 budget. CDC's overall budget authority has not been this low since 2003.

At the National Center level, Dr. Khabbaz will continue to serve as the Acting Director of NCHHSTP until Dr. Kevin Fenton's permanent replacement is appointed. Dr. John Moore will continue to serve as the Acting Director of the Division of Adolescent and School Health until Dr. Howell Wechsler's permanent replacement is appointed. Searches are underway to fill both of these leadership positions in NCHHSTP.

NCHHSTP learned from stakeholder feedback that its web-based "Atlas" is continuing to increase public access to data across all HIV/AIDS, viral hepatitis, STD and TB programs ([www.cdc.gov/nchhstp/atlas](http://www.cdc.gov/nchhstp/atlas)). NCHHSTP will launch a new "Prevention Through Health Care" website in the near future to assist its funded health departments in taking advantage of key provisions in ACA. NCHHSTP published a supplement to the *Public Health Reports on Sexual Health* in February 2013.

The Presidents' FY2014 budget requested a total of \$1.177 billion for NCHHSTP. The request is equivalent to a net increase of \$14 million over the FY2012 budget. The majority of the increase is for domestic HIV surveillance activities and an evaluation of school-based health prevention efforts. The STD, viral hepatitis and TB budgets are nearly level with the FY2012 budget, but funding for viral hepatitis that was from the 2012 Prevention and Public Health (PPHF) budget is now in base budget request.

At the division level, the NCHHSTP Division of STD Prevention (DSTDP) is continuing to make tremendous progress in broad public outreach through social media. DSTDP's Twitter account, @CDCSTD, reached 15,000 followers in March 2013. The DSTDP website was the most popular of all CDC.gov websites in 2012 based on 28 million visits.

DSTDP experts led the CDC Public Health Grand Rounds in February 2013, "Reducing the Burden of Human Papillomavirus (HPV)-Associated Cancer and Disease Through HPV Vaccination in the United States." All Grand Rounds are available on the CDC.gov website for public health professionals to review and obtain continuing medical education credits.

DSTDP updated the national STD estimates in March 2013. Data show that 20 million new infections in the United States each year are equivalent to a financial burden on the American healthcare system of nearly \$16 billion. This estimate accounts for 110 million incident and prevalent STDs among men and women nationwide. The data further show that HPV accounts for the majority of newly acquired STDs.

DSTDP is conducting multiple activities with both domestic and global partners to address drug-resistant gonorrhea. Surveillance of gonorrhea resistance is continuing through the Gonococcal Isolate Surveillance Project (GISP). The program is collaborating with the World Health Organization to improve communication about gonorrhea-resistant threats among international partners and increase detection of gonorrhea by supporting global laboratory infrastructures; with the CDC Office of Antimicrobial Resistance (OAR) to develop an agency-wide antimicrobial resistance report; with OAR and the Food and Drug Administration (FDA) to support the inclusion of *Neisseria gonorrhoeae* as a "qualifying pathogen" in the Generating Antibiotic Incentives Now Act of 2011; with the NIH National Institute of Allergy and Infectious Diseases on a clinical trial of two antimicrobial combinations for the treatment of gonorrhea; and with the Harvard School of Public Health to perform whole-genome sequencing of GISP isolates.

DSTDP released a new funding opportunity announcement (FOA) on June 14, 2013, "Improving Sexually Transmitted Disease Programs Through Assessment, Assurance, Policy Development and Prevention Strategies." The revised funding formula in the FOA will provide grantees with greater flexibility to directly target their resources to areas based on local needs.

The grantees will be funded to target activities to four distinct populations: adolescents/young adults, men who have sex with men (MSM), persons with multidrug-resistant gonorrhea, and persons with congenital syphilis. The grantees will conduct activities in two categories. Part A activities will focus on STD prevention strategies for implementing high-impact, cost-effective and sustainable STD prevention services. Part B activities will focus on GISP.

The NCHHSTP Division of HIV/AIDS Prevention (DHAP) expanded its HIV awareness and anti-stigma campaign, "Let's Stop HIV Together™." In addition to a new Spanish version of the

campaign, more participants, materials and information on HIV awareness and testing also have been included.

Among other presentations by DHAP staff during the March 2013 Conference on Retroviruses and Opportunistic Infections, an analysis showed that a significantly greater proportion of HIV-positive MSM in 20 cities were aware of their infections in 2011 (66%) compared to 2008 (56%); and a study showed that health insurance coverage helps patients in HIV care to achieve viral suppression.

DHAP is continuing to make progress in better aligning health department prevention funds to the HIV epidemic. The funding formula allows flexibility based on local epidemic modeling and needs. CDC's annual allocations totaling \$359 million to 68 health departments are based on HIV prevalence. HIV prevention resources will closely match the geographic burden of HIV after the new funding formula is implemented. DHAP is also continuing its efforts to advance integration of surveillance and program activities at both public health and clinic levels to ensure that all persons living with HIV (PLWH) are prescribed antiretroviral therapy (ART) and remain in care.

The NCHHSTP Division of Adolescent and School Health (DASH) collaborated with DHAP to publish a *Vital Signs* Report in December 2012 on youth and HIV. The report noted that young persons 13-24 years of age accounted for 25% of new HIV infections in 2010. Of ~1,000 young persons who are infected with HIV each month, the majority have no knowledge of their status.

The report further noted that young MSM were more likely to engage in HIV-related risk behaviors than other males and females and also were less likely to be tested for HIV. The first "National Youth HIV/AIDS Awareness Day" was held on April 10, 2013. Dr. Howell Wechsler, the former Director of DASH, participated in an event on Capitol Hill to commemorate this day.

The NCHHSTP Division of Viral Hepatitis (DVH) initiated hepatitis testing and referral-to-care activities in all 35 sites supported by PPHF. The Viral Hepatitis Action Coalition provided support to convene a series of meetings with diverse stakeholders to implement CDC's HCV testing recommendations for the 1945-1965 birth cohort.

DVH partnered with the NIH National Institute on Drug Abuse to organize a consultation to determine the best strategies to respond to the recent increase in HCV infections among injection drug users (IDUs) in general and young persons <30 years of age in particular. DVH sponsored a number of activities to recognize "Hepatitis Testing Month" in May, including publication of a *Vital Signs* Report on May 6, 2013 related to hepatitis testing and participation in a Congressionally-sponsored hepatitis event. DVH launched the "Know Hepatitis B" Campaign on June 12, 2013 that is targeted to Asian Americans and Pacific Islanders.

## HRSA/HAB Associate Administrator's Report

### **Laura Cheever, MD, ScM**

(Acting) Associate Administrator and Chief Medical Officer, HIV/AIDS Bureau  
Health Resources and Services Administration  
CHAC Designated Federal Officer, HRSA

Dr. Cheever covered the following topics in her Associate Administrator's report to CHAC. HAB is continuing to monitor implementation of ACA and its impact on the Ryan White HIV/AIDS Program (RWP). To ensure a seamless transition to ACA for RWP clients who will have access to expanded coverage, HAB is educating RWP providers and grantees about opportunities under ACA. HAB is closely collaborating with HHS to identify changes that will be needed in RWP as ACA is implemented over time. However, the Obama Administration has explicitly stated that full implementation of ACA will not eliminate the need for RWP.

RWP currently is authorized through September 30, 2013. After this date, however, RWP will not sunset and can continue to operate through Congressional appropriations with or without subsequent legislation. Although Congress will have final decision-making authority on whether or not to pursue reauthorization of RWP, the Obama Administration strongly supports RWP and continuation of its services. Moreover, the Administration recognizes the need to continue RWP as progress is made on full implementation of ACA. The critical role of RWP in improving outcomes along the continuum of care (*i.e.*, the "Treatment Cascade") is recognized at the highest levels of government.

HAB has made several accomplishments in four key areas to promote administrative flexibility, provide guidance, and prepare RWP grantees for a seamless transition to ACA. For "grantee communications," HAB launched an RWP-ACA Mailbox in January 2013 for grantees to submit questions that will be discussed with HHS and the Centers for Medicare and Medicaid Services (CMS).

HAB launched an ACA webpage in March 2013 that is regularly updated with new information, guidance, policies and tools to assist with the ACA transition. HAB launched an ACA-specific section on its TARGET Center website in March 2013. This website serves as an inventory of tools for the RWP community. HAB added a new "ACA Update" feature to its biweekly e-mail. HAB is continuing to hold quarterly meetings with national partners. The most recent meeting in April 2013 focused on outreach, enrollment and other ACA implementation issues.

For "policy development," HAB is reviewing existing policies and making necessary revisions in the context of ACA. HAB will develop and issue additional policies in the future pending final approval and clearance, but several new policy notices, clarification notices of existing policies, and other ACA-related information already have been posted for RWP grantees:

- ACA Outreach and Enrollment Letter
- Key Provisions of ACA for RWP Providers
- Letter to Essential Community Providers (using a non-exhaustive list)
- Updated Policy on Client Medicaid Eligibility
- Updated Policy on Client Recertification Requirements
- Joint HRSA-CMS Document: “Coordination Between Medicaid and RWP Clinics”
- *Federal Register* Notice: Core Services Waiver

For “training,” HAB launched a series of ACA training sessions to ensure that internal Project Officers provide RWP grantees with accurate answers to questions. HAB is collaborating with CMS to continue to co-host a series of webinars for RWP grantees:

- “The Affordable Care Act and the Ryan White HIV/AIDS Program: Eligibility 101” (April 5, 2013)
- “Potential Impacts of the Affordable Care Act on Ryan White Providers in 2014” (May 7, 2013)
- “Ryan White Providers and Medicaid: Preparing for 2014 (June 25, 2013)

For “technical assistance (TA) and development of tools,” HAB is partnering with the HRSA Outreach and Education Workgroup to ensure that RWP grantees have the capacity to assist clients in enrolling in new health insurance options. HAB is drafting an extensive list of “frequently asked questions” to address common ACA questions. HAB will issue contracts to develop other tools that will be needed by RWP grantees and clients. HAB will establish a new “Technical Assistance Resource Center” to assist RWP grantees with ACA-related outreach and enrollment activities.

HAB established several priorities for FY2013 to advance the goals of the National HIV/AIDS Strategy (NHAS) and achieve an “AIDS Free Generation.” PLWH will be engaged and retained in care to improve health outcomes. Numerous activities will be conducted to prepare RWP grantees and HAB staff for full implementation of ACA. RWP client-level data will be analyzed and disseminated. RWP and President’s Emergency Plan for AIDS Relief (PEPFAR) grantees will continue to be funded and monitored. Important HIV/AIDS initiatives will continue to be supported both domestically and internationally:

- Quality initiatives and Special Projects of National Significance (SPNS)
- UCARE<sub>4</sub>LIFE to better reach, engage and retain HIV-positive adolescents in care and treatment via texting
- HIV workforce issues (e.g., the HIV Workforce Study, Medical Education Partnership Initiative, and Nursing Education Partnership Initiative)
- The initiative to share and incorporate lessons learned between global and domestic HIV programs

Several changes have occurred in HAB's leadership since the December 2012 CHAC meeting. Dr. Deborah Parham Hopson, Associate Administrator of HAB, accepted a new position as the Senior Advisor for HIV/AIDS to the HRSA Administrator. Dr. Cheever will serve as the Acting Associate Administrator of HAB until Dr. Parham Hopson's permanent replacement is appointed.

Ms. Sylvia Trent-Adams is serving as the Acting Deputy Associate Administrator of HAB. Ms. Cynthia Grubbs is serving as the Acting Senior Advisor to the HAB Associate Administrator. Mr. Everett Lott was appointed as the HAB Executive Officer and Director of the Office of Operations and Management. Several new Project Officers and Branch Chiefs were appointed to HAB as well.

Dr. Cheever established priorities for HAB in four key areas to ensure that the quality of HIV/AIDS care and treatment is improved during the transition to new leadership: ACA implementation; internal and external customer service; interagency collaborations and external partnerships with national stakeholders; and capacity-building related to the collection, analysis and dissemination of client-level data.

In terms of client-level data, the 2010 and 2011 Ryan White Services Reports showed remarkably similar outcomes. Of 555,762 clients who were served in 2010 and 553,766 clients who were served in 2011 by gender, males accounted for ~69% of RWP services, females accounted for ~30% of RWP services, and transgenders accounted for <1% of RWP services. Of 543,075 clients who were served in 2010 and 540,192 clients who were served in 2011 by race/ethnicity, non-Hispanic blacks accounted for ~47% of services, whites accounted for ~28% of services, and Hispanics accounted for ~22% of services.

By core medical services, outpatient ambulatory medical care (~57%), medical case management (~53%), oral health care (~16%), mental health (~14%), and medical nutrition care (8%) accounted for the top 5 services provided to RWP clients in 2010 and 2011. By support services, non-medical case management (~26%), transportation (~14%), health education/risk reduction (~12%), food bank/home delivered meals (~11%), and emergency financial assistance (~5%) accounted for the top 5 services provided to RWP clients in 2010 and 2011. HAB hopes that the final client-level data will be cleared for release later in the summer of 2013.

HAB is continuing to conduct quality management activities based on its performance measures that cover various aspects of HIV care and treatment. Most notably, HAB closely collaborated with CDC to obtain national endorsement and approval from the National Quality Forum (NQF) on four HIV performance measures: the frequency of HIV medical visits, gaps in HIV medical care, prescriptions of ART for HIV, and HIV viral load suppression. HAB is pleased that 3 of its 4 NQF-endorsed measures were included in the HHS Secretary's parsimonious list of measures for all HHS HIV programs.

HAB will sponsor two webinars on June 20 and June 25, 2013 to gather input from stakeholders to further revise, streamline and decrease the number of performance measures and ensure consistency with and alignment across federal programs. HAB will continue efforts to include its measures in CMS Meaningful Use Stage 3 criteria for use nationally and in sites outside of the federal government.

HAB awarded cooperative agreement (CoAg) funds to Health Research, Inc. and the New York State AIDS Institute to establish the National Quality Center (NQC). Over the five-year project period from August 2012 to June 2017, the grantees will conduct several activities to support the NQC (e.g., training and TA, quality management coaching, learning collaboratives with 135 grantees representing 38 states, and the In+Care Campaign to improve retention in care).

HAB is funding two new SPNS Initiatives in FY2013: (1) culturally-appropriate interventions of outreach, access and retention among Latino populations and (2) health information technology (HIT) capacity building initiatives for RWP AIDS Drug Assistance Program (ADAP) grantees. HRSA announced that the FY2013 budget included a 5% reduction in funding across all RWP programs. HAB asked all RWP grantees to reprioritize their existing activities and identify areas that can be cut to absorb the 5% reduction in funding.

CHAC discussed the following topics in the question/answer session with Drs. Khabbaz and Cheever on the CDC/NCHHSTP and HRSA/HAB updates.

- HAB's plans to develop guidance for states in which Medicaid expansion is not occurring.
- CDC's plans to overcome barriers to the potential impact on treatment as prevention in states that are not expanding Medicaid, particularly in areas with high populations of PLWH in poverty.
- HAB's plans to assist RWP grantees in helping their clients transition to a patient-centered medical home (PCMH) model.
- HAB's progress in the care and treatment of RWP patients who are co-infected with HIV/HCV.
- Joint efforts by CDC and HRSA (e.g., the "Care and Prevention in the United States" demonstration project) to build the capacity of their grantees in shifting from a siloed, jurisdiction-specific approach to a broader strategy that promotes integration of planning and continuum of care activities.

The question/answer session resulted in CHAC making several suggestions for CDC and HRSA to consider in improving their prevention, care and treatment initiatives.

- HAB should conduct quality studies to document the impact on access to and availability of HIV providers and continued high-quality HIV care if RWP is eliminated after ACA is implemented. HAB should design these studies to determine the extent to which HIV-

specific expertise is available among primary care providers (PCPs) in various communities.

- HAB should make stronger efforts to apply lessons learned and experiences from PEPFAR programs in Africa and other parts of the world to domestic programs related to scaling up HIV care and treatment. PEPFAR programs place much stronger emphasis on task shifting in which trained personnel with limited expertise provide HIV care, while domestic programs require a physician, physician's assistant, nurse practitioner or other highly-skilled provider to care for HIV patients. Compared to domestic programs, HIV care in PEPFAR programs is simpler and much more streamlined due to minimal bureaucracy and paperwork.
- HAB's guidance to RWP grantees should describe culturally-sensitive strategies and evidence-based best practices to reach, engage and retain the lesbian/gay/bisexual/transgender (LGBT) population in HIV care.
- HAB should take leadership in a multi-agency effort to compile and review existing data from CMS, private payers and other sources to determine the quality of care that is provided by HIV programs. This effort would allow the agencies to develop a more complete picture of the overall quality of care and better identify gaps in the HIV workforce.
- HAB should extensively consult with federal partners in its ongoing efforts to revise and improve the performance measures. First, HAB should engage CDC in discussions on revising the measures to prevent the transmission of infection from PLWH in care. Most notably, the measures have a limited focus on HIV care from a biomedical perspective. Despite the incidence of 40,000-50,000 new STDs from HIV-positive persons in the United States each year, HIV viral load suppression is the only measure that addresses prevention. However, this measure does not reflect genital viral load suppression. Second, HAB should engage SAMHSA in discussions because none of the measures address mental health and substance abuse. A number of studies have demonstrated that these two issues tremendously contribute to the proportion of PLWH who are not engaged or remain in care.
- CDC and HRSA should perform an analysis to identify extraordinary opportunities that ACA will provide in Medicaid expansion and other areas and also to determine gaps in this regard. The analysis should be designed to identify specific areas in CDC-funded high-impact HIV prevention activities and HRSA-funded care services that health insurance will and will not cover. The analysis also should focus on health insurance coverage that will be needed in three distinct constructs to accomplish public health objectives in terms of communicable diseases: public health settings, medical settings, and community-based organization (CBO) or other non-medical settings.

## Panel Presentation: Challenges/Opportunities of STD Clinical Preventive Services

### **Gail Bolan, MD**

Director, NCHHSTP Division of STD Prevention  
Centers for Disease Control and Prevention

#### **Advice Requested from CHAC by DSTDP:**

- What are the best strategies to scale-up and routinize STD clinical preventive services in primary care and HIV care settings? Should incentives be given to providers?
- What are the best strategies to take advantage of electronic medical records (EMRs) and clinical decision support systems to enhance implementation of STD clinical preventive services in primary care and HIV care settings?
- What are the best strategies to improve the collection of clinical care data to monitor impact and improve meaningful use of data?

Dr. Bolan explained that this topic was placed on the agenda for CHAC to consider proposing a formal recommendation/resolution regarding the challenges and opportunities of integrating STD clinical services in HIV care clinics, Federally Qualified Health Centers (FQHCs) and other primary care settings. She announced that CDC recently issued a new FOA for its funded state/local health departments to conduct STD prevention activities and initiate efforts to integrate public health and primary care in the evolving healthcare environment.

To inform CHAC's decision-making process, Dr. Bolan introduced two keynote speakers who were invited to the meeting to describe their efforts, observations and experiences in the field to integrate public health prevention and primary care activities.

### **Daniel Miller, MD**

Chief of Clinical Quality and Training  
Hudson River HealthCare

Dr. Miller presented a clinical perspective of integrating primary care and prevention in FQHCs in his portion of the panel presentation. Hudson River HealthCare (HRHCare) was established in 1975 in Peekskill, New York. Since 1975, HRHCare and its sub-recipients have evolved into a large FQHC with 23 Community Health Centers (CHCs) in 9 New York State counties that serve ~96,000 patients.

Of all HCHCare patients, 41% prefer Spanish or other non-English languages, 50% are below the Federal Poverty Level, 33% are uninsured, and 33% receive Medicaid. HRHCare's current status and resources include recognition as a Level 3 National Committee for Quality Assurance (NCQA) PCMH, Joint Commission accreditation, designation as a New York State Health

Home, HRSA funding as a RWP grantee, and recipient of a medical home subsidy and HCV grants.

HRHCare has a long history of conducting quality improvement (QI) initiatives, particularly its early adoption of EMRs in 2005. HRHCare has learned that good ideas are necessary, but are not sufficient to achieve actual change. HRHCare also has learned that medical providers do not change practices because of being told, taught or informed of good ideas.

Transformation is needed to achieve actual change and requires a systemic approach with multiple factors: multi-level interventions and decision support, EMRs, alerts, templates, order sets, workflow and redesign of teams, ongoing feedback and data, and incentives from emotional, intellectual or monetary perspectives. However, transformation is extremely tiring and results in “change fatigue” among clinicians.

HRHCare is a PCMH that aims to improve care and lower costs. However, the 2009 Yarnall, *et al.* study reported that the amount of time for providers to meet current clinical guidelines is insufficient. For example, PCPs would need ~22 hours each day to adhere to all of these recommendations. PCPs typically devote ~25%-33% of a patient visit to documenting their actions.

Clinical guidelines should be recommended for implementation only if a meaningful impact would be achieved. To institutionalize improvement with actual systemic changes, priorities should be established; tools should be created (e.g., alerts, templates and order sets); the workflow should be clearly defined; reports should be developed; a team should be extensively engaged at the outset for feedback and necessary revisions; and the “plan-do-study-act” approach should be taken.

PCPs typically review CDC data to focus on the most important issues from a clinical perspective. Heart disease, cancer, chronic lung disease and stroke are among the top 10 leading causes of death in the United States. Smoking, poor diet/physical inactivity and alcohol consumption are primary contributing factors to these diseases.

In terms of prevention, 14 major studies on the impact of a healthy lifestyle were reviewed. The review led to the development of a “formula for good health” with the following components: no smoking, 5 servings of fruits and vegetables per day, 10 minutes of relaxation, body mass index <30, and 150 minutes of exercise per week. Persons who apply the formula for good health have better outcomes than any intervention prescribed by a physician. As a PCMH, HRHCare provides the formula for good health to each patient at every visit and uses its EMR system to document the progress of each patient in all 5 areas over time. This approach allows HRHCare to integrate prevention in a clinical model.

In terms of communicable diseases, HRHCare prioritized prevention through sexuality, condom use and a focus on adolescents; HIV, HCV and chlamydia screening and treatment; and pregnant women. HRHCare provides a number of tools to assist clinicians in addressing these priorities, such as prenatal order sets, templates for well child visits, templates and order sets for HIV and HCV care, and templates for adolescents with questions on sex, condom use, substance use, birth control methods and STD history. Alerts are built into the EMR system for HIV and HCV screening, but HRHCare is aware of the need for EMR designers to develop their systems to be more responsive to clinical needs.

HRHCare's PCMH model includes a robust team of case managers, PCPs, infectious disease and other specialty providers, psychiatrists and social workers, adherence nurses, nutritionists, peer and group support, and laboratory technicians. Based on January-June 2011 data, HRHCare's PCMH model and clinical tools have resulted in tremendous success in patients achieving viral load suppression. However, HRHCare recognizes that small practices without its same size, scope, tools, robust team and other resources cannot duplicate this degree of success.

HRHCare distributes a clinical quality dashboard to all of its providers to measure their performance based on numerous benchmarks for their patients: lifestyle choices, chronic diseases, infectious diseases, pediatric outcomes, depression and safety. The measures are colored in either red or green on the dashboard to illustrate to providers whether their performance is acceptable or unacceptable.

HRHCare has identified several challenges to serving as a PCMH, including the provision of team-based care with all members of the team functioning at the "top of their licenses," time constraints, change fatigue and the burden associated with documentation. Moreover, EMRs need to be redesigned to be fully functional with customizable decision support tools, reminders for targeted screening, alerts, templates and order sets, and a process to share best practices.

HRHCare is a large FQHC with EMR developers and trainers, report and grant writers, QI staff, infectious disease specialists, and Ryan White funding and HCV grants. However, small practices without these resources will be unable to serve as a PCMH. To enhance the partnership between prevention and primary care, the ability to actually implement clinical guidelines in the field should be thoroughly considered when these recommendations are developed.

National priorities should be designed to be "patient-centered" rather than "disease-centered." Existing requirements that are not based on or supported by evidence should be eliminated. Information technology and practice support should be provided. Best practices should be nationalized with higher standards for EMRs that include alerts, templates, order sets and reports.

**David Stevens, MD, FAAFP**

Director, Quality Care

National Association of Community Health Centers

Dr. Stevens presented a national perspective of STD prevention in CHCs in his portion of the panel presentation. CHCs need several resources from health departments. Information should be transferred, including community assessments and prevalence data to describe the extent of the problem. Benefits and resources should be coordinated and shared, including test kits, screening tools, data charts, training, DIS coordination, partner notification and expedited therapy, and facilitation of care coordination and access to specialists. The integration of HIV and STD into a PCMH model should be supported.

Health departments also need resources from CHCs. Health departments should understand that CHCs are an untapped market and a vital service to the safety net. CHCs play a critical role in HIV and STD screening of high-risk groups. Health departments should partner with state Primary Care Associations to build relationships with CHCs and enhance their knowledge of the roles and responsibilities of CHCs. State partners and program managers should provide national support. State Primary Care Associations are positioned to advocate for medical and pharmacy needs. Specialty boards for expedited partner therapy and other issues also serve as an extremely helpful resource.

The 2011 National Strategy for Quality Improvement in Health Care is based on three overarching principles: better care, healthy people/healthy communities, and affordable care. The National QI Strategy priorities include safety, engagement of individuals and families, effective communication and coordination of care, effective prevention and treatment practices for the leading causes of mortality (e.g., cardiovascular disease), community partnerships to promote wide use of best practices for healthy living, and affordable quality care through the development and dissemination of new care delivery models.

Infectious diseases are not mentioned in any of the National QI Strategy priorities, but the Institute of Medicine (IOM) report on public health and primary care described several provisions in ACA with potential opportunities. For example, Community Transformation Grants can be linked to CMMI demonstration projects and state health reform initiatives. Community health needs assessments can be linked to community health benefits and inform state health reports.

Medicaid preventive services can lead to the development of joint guidance and assistance to Medicaid providers. Medicaid expansion and insurance exchanges can target and enroll risk-eligible populations and assure prevention services. CHCs can be linked to local public health, prevention activities and decision support for chronic and infectious diseases. Accountable care organizations (ACOs) and PCMHs can strengthen the public health partnership in ACO and PCMH development and measurement.

ACOs have developed 33 quality performance standards in four areas to improve care and population health: patient/caregiver experience (7 standards), care coordination and patient safety (6 standards), prevention (8 standards), and at-risk populations (12 standards). Medicaid and the Children's Health Insurance Program have developed a core set of child healthcare measures in the following domains: population and community health, clinical care, care coordination, safety, efficiency and cost reduction, and person/caregiver experience. HRSA has developed Uniform Data System (UDS) metrics in an effort to align these various sets of measures, including Meaningful Use criteria.

ACOs are public/private collaborations with multiple stakeholders in which providers assume responsibility for overall patient care across clinicians and settings over time. ACO configurations can vary to reflect the diversity of local healthcare markets and preferences of participants: integrated delivery systems, physician-hospital organizations, physician group practices, Independent Practice Associations, or regional collaboratives.

However, all ACOs must be designed with three essential characteristics: (1) the ability to provide or manage continuum of care to a defined population over time and across settings as a real or virtually integrated delivery system; (2) a sufficient size to support comprehensive and continual performance measurement of cost and quality outcomes; and (3) capacity to prospectively plan budgets and address resource needs.

CHCs were used as sites to launch a five-year demonstration project of the PCMH and Safety Net Initiative. The project resulted in the identification of four change concepts to achieve practice transformation. A "change concept" is defined as an idea that is used to stimulate specific and actionable steps leading to improvement. The four change concepts are:

- establishing a foundation through engaged leadership and QI strategies;
- building relationships through empanelment and continuous, team-based relationships;
- changing care delivery through patient-centered interactions and organized, evidence-based care; and
- reducing barriers to care through enhanced access and care coordination.

Tools were developed for each of the four change concepts and are publicly available at no charge. All of the change concepts are relevant to the care of persons with HIV, HCV and STDs. However, the perspective of the National Association of Community Health Centers (NACHC) of the PCMH model and safety net is much broader than the four change concepts. NACHC focuses on three guiding principles that are necessary for a health reform framework: improvement of population health and a reduction in disparities; engagement and activation of patients, families and communities in health; and superior cost and quality outcomes.

The specific components of the NACHC health reform framework for PCMHs are PCMH recognition and accreditation programs; integration of Meaningful Use measures and the HIT

infrastructure; integration of oral, behavioral/mental health and HIV/AIDS care; and engagement of CHCs in local health systems and community health improvement initiatives.

Preliminary results of the demonstration project of the PCMH and Safety Net Initiative are promising. CHCs in Alaska, Minnesota, Maryland, New Jersey and Vermont reported fewer urgent care and emergency department (ED) visits, fewer hospital admissions, a reduction in the utilization of specialists, shorter wait times for appointments, an increase in patient self-management capacity, a decrease in overall health costs to patients, a reduction in inpatient services, cost-savings to the entire healthcare system, and lower monthly costs for each member.

Several strategies have been implemented to align the components of a PCMH model with Meaningful Use measures:

- electronic prescribing of patient medication lists and allergies;
- patient tracking through a data registry that includes demographics, diagnoses, vital signs, smoking status, population management and insurance status;
- care management with reminders for follow-up care, decision support and treatment reconciliation;
- enhanced electronic capabilities, including e-health information to patients, summaries of patient visits, e-access to health information, and exchange of information among providers; and
- ongoing reporting of provider performance to assure QI.

The design of the PCMH model includes six major components. The “access and outreach” component invites persons into primary care practice and targets high-risk populations (e.g., adolescents). The “sorting” component evaluates the risk of patients and assures continued care with their providers (e.g., a routine sexual health history and assessment). The “provision of best care” component ensures that patients will be given evidence-based comprehensive care (e.g., HIV, HCV and STD screening and follow-up).

The “involvement” component builds the capacity of patients to self-manage their conditions and remain in care (e.g., collaboration and support for patients to establish sexual health goals). The “ongoing tracking” component coordinates care, tracking and outreach activities through public health partnerships and other resources. The “ongoing improvement” component measures the performance and QI of practices (e.g., a practice performance assessment on sexual health metrics).

Drivers of the PCMH model that specifically are targeted to FQHCs and can be leveraged in ACA have been developed by a number of sources. HRSA’s PCMH initiatives include external accreditation and recognition programs, one-time supplemental funding in 2011, and policy direction in grants and CoAgs.

CMS funded an advanced primary care demonstration project in FQHCs. Support was given to the Commonwealth Fund and Qualis Health Safety Net Medical Home demonstration projects and the NACHC Patient-Centered Medical Home Institute. Initiatives were funded to expand the existing infrastructure that was built by the Health Disparities Collaborative, Wagner Care Model, QI science activities, and state-based QI capacity. The 2012 Takach study reported that Medicaid also offers payment incentives for PCMH transformation and practice in primary care settings. All of these FQHC-focused initiatives made efforts to incorporate Meaningful Use measures.

The Robert Wood Johnson Foundation funded a study to assess the needs of small Medicaid practices in four states to improve health outcomes of their diabetic patients. The needs most commonly reported by the grantees were provision of data; funding and support to customize existing EMR systems to address local needs; availability of care management resources to enhance outreach to and tracking of patients; and facilitation to improve the workflow and strengthen financial management capacity to assure the viability of the practice. Other small practices most likely could apply these same principles to improve the health outcomes of their HIV, HCV and STD patients.

The grantees used their initial funding at specific milestones to establish learning collaboratives to interact and exchange ideas with other providers and conduct other activities. NACHC's interpretation of the study findings indicates that after a full year of ACA implementation in 2015, the number of Medicaid patients will increase and the significant number of uninsured patients will persist.

NACHC developed a series of questions and criteria to assist its member CHCs in achieving NCQA recognition as a PCMH with the help of health departments.

- Can the health department help the CHC in assessing its population, selecting three important conditions, and implementing evidence-based guidance for each condition? Of the three selected conditions, one must be related to unhealthy behaviors or mental health/substance abuse issues.
- Can the health department help the CHC in selecting three preventive care measures, three chronic or acute care measures, and two utilization measures? Can the health department help the CHC in stratifying these data to assess disparities in care?
- Can the health department help the CHC in supporting patients to access referrals to community resources?

The Oregon Coordinated Care Organization (CCO) serves as an example of a Medicaid ACO. This state-based prevention model includes the following key components: a PCMH, local control and coordination, health equity, metrics and performance measures, global budgets and shared savings, incentive programs, and Community Advisory Councils. Because the health

department is a key component in the Oregon CCO, shared savings have been applied to address housing issues and other public health initiatives across the state.

The Oregon CCO is designed to improve population health outcomes in the overall healthcare system, primary care, public health, community prevention, social determinants of health, education, and services provided by payers, insurers and ACOs. Moreover, the Oregon CCO addresses the “triple-aim” framework of improved population health, better health outcomes and lower healthcare costs.

The Oregon CCO also has made a commitment to adhere to CMS’s core metrics in its health system transformation. The goals of the Oregon CCO in this effort are to reduce the annual increase in the cost of care by 2 percentage points; improve quality care and population health; establish a quality incentive pool that will increase each year as a percentage of the global budget; maintain a strong commitment to measurement; and assure ongoing reporting of CCO metrics to the public.

Dr. Stevens presented data to illustrate the success of the Oregon CCO in primary, secondary and tertiary prevention in both insured and uninsured diabetic patient populations in Multnomah County. NACHC hopes that the state health department will apply the framework of the Oregon CCO to improve health outcomes of HIV, HCV and STD patients.

Overall, health reform is creating a healthcare marketplace to provide access and quality care to persons that can evolve into a “health marketplace” to support a vital and healthy population. Health reform is playing an important role at state and marketplace levels with opportunities for alignment with national policies and priorities. Public health cannot initiate partnerships with new health systems on a categorical, disease- or prevention-focused basis. Instead, public health needs to build relationships based on health reform drivers of access, cost and quality and provide leadership and flexibility to achieve this goal.

The components needed to achieve population-based health and sustain system-wide impact over time include a solid strategy, robust structure, cultural changes and technical expertise. NACHC is informing its member CHCs of priorities that will need to be met to achieve success in the new ACA environment: providing bold leadership to align national and local strategies; linking primary care practice transformation to outcomes; continuing to innovate the PCMH model; strengthening support and partnerships for the existing infrastructure; and leveraging national and state health reform.

CHAC discussed the following topics in the question/answer session with Drs. Bolan, Miller and Stevens on the challenges and opportunities of integrating STD clinical preventive services in CHCs and HIV care clinic settings.

- The elimination of STD treatment facilities in multiple jurisdictions across the United States.
- Priority issues that have been established for EMRs, but do not reflect improvements in the quality of care.
- Efforts by healthcare systems and CHCs to ensure that HIV, HCV and STD prevention, care and treatment are not diluted in the routine practice of addressing heart disease, diabetes, cancer, obesity and other competing health priorities.
- Strategies to bridge the disconnect, persistent gaps and differences between the primary care and public health/infectious disease prevention cultures, particularly the omission of sexual behaviors and sexual orientation issues in primary care settings.
- The need for a stronger focus on task shifting in domestic programs. (For example, other countries deliver prevention, care and treatment services at a much lower cost and achieve much greater impact than the United States.)
- Application of domestic and global experiences, lessons learned and successes in integration, collaboration and partnerships to achieve a greater impact in the delivery of health care, particularly in the upcoming ACA environment.
- Traditional silos of HIV/AIDS, hepatitis and STD programs that serve as a barrier to cross-functional synergy and public health integration even though these independent programs typically serve the same populations.
- Minimal interaction of local health departments with CHCs to help define priorities and identify collaborative opportunities.
- The need for increased emphasis on racial/ethnic minority groups in efforts to integrate STD preventive services in CHCs and HIV care clinics:
  - Accurate interpretation of data and prioritization of issues that reflect significant disparities in HIV morbidity among African Americans due to the tremendous contribution of this population to overall healthcare system costs.
  - The important need to design culturally-specific and relevant activities to outreach to and engage multiple populations in care (e.g., Hispanics, Native Americans, Pacific Islanders, and immigrants/refugees of African countries).
  - The need for a more detailed breakdown of racial/ethnic groups in community health assessments to illustrate an actual nationally representative sample (e.g., inclusion of Puerto Rico, the U.S. Virgin Islands, and the large Hispanic population in the state of Florida).

CHAC thanked Drs. Miller and Stevens for taking valuable time from their busy practices to attend the meeting and describe their clinical and national perspectives of integrating public health STD preventive services in healthcare settings. The question/answer session resulted in the CHAC members making several suggestions for CDC and HRSA to consider in this regard.

- CDC and HRSA should promote STD prevention and treatment as a consolidated package of services for practitioners to address outside of health departments. The

federal partners also should design a co-management model for HIV/HCV/STD experts to educate and train small health centers in addressing these diseases.

- Clinical data exchanges and other group-based resources that utilize the same systems should be designated to review STD data, share best practices, and exchange templates and other tools. A more user-friendly data system should be developed to support this effort.
- A national effort should be launched to promote changes in medical school and nursing school curricula to ensure that students are given education and training on sexual health issues. In the interim, HRSA should allocate more funding to AIDS Education and Training Centers (AETCs) in order for providers to feel more comfortable in discussing sexual health, STDs, and the relationship between HIV and STD transmission with their patients.
- HRSA should fund a study or perform an analysis to determine the systematic approach or decision-making process of CHCs in selecting interventions to assure the best health outcomes of their patients.

Dr. Bolan thanked CHAC for its rich discussion and thoughtful insights on the challenges and opportunities of integrating STD clinical preventive services in healthcare settings. She also appreciated CHAC's candor in addressing the tension between the public health and healthcare cultures. She asked CHAC to consider the following issues in proposing a recommendation/resolution in this regard to HHS, CDC and/or HRSA.

Important system changes will occur at the state level rather than federal level. An integrated approach is needed with diverse expertise at multiple levels. Strategies are needed to leverage public health dollars to scale-up prevention in the healthcare system, while approaches are needed to leverage healthcare dollars to scale-up the public health model for infectious diseases. A "public health patient" definition is needed for public health agencies to obtain reimbursement for their activities to protect the health of communities.

Dr. Marrazzo also summarized key points from the discussion for CHAC to consider in drafting a recommendation/resolution on the integration of STD clinical preventive services in healthcare settings. First, EMRs are tremendously valuable tools. Efforts should be made to take advantage of this resource to improve the provision of clinical support and delivery of interventions with known effectiveness.

Second, "better" care in the context of primary care should be clearly defined. For example, the HRHCare clinical model that drives the majority of its activities and metrics primarily is focused on morbidity and mortality, while STD and sexual health activities focus on quality of life. A paradigm shift and effective system changes will be needed to enhance the care and prevention of STDs in clinical settings in this context. Third, HRHCare's lessons learned, experiences and challenges in providing STD care in a PCMH model should be compiled and widely disseminated as guidance for other healthcare systems.

## Panel Presentation: Challenges/Opportunities in the Test and Cure Era for Hepatitis C

### John Ward, MD

Director, NCHHSTP Division of Viral Hepatitis  
Centers for Disease Control and Prevention

#### Advice Requested from CHAC by DVH:

- What are the implications for primary care practice based on differences or agreement between CDC and U.S. Preventive Services Task Force (USPSTF) HCV screening recommendations?
- What role should PCPs assume in HCV management? What are the challenges in providing these services? What are the best strategies to address these challenges? Issues to consider include linkage to care, laboratory services and the need for specific expertise (e.g., management of side effects and an assessment of response to treatment).

Dr. Ward presented an overview of the public health response to the HCV epidemic in his portion of the panel presentation. Data from CDC and other studies have been collected to predict the future burden of HCV-related morbidity and mortality in the United States. Of 2.7 million HCV patients in primary care, 1.47 million will develop cirrhosis, 350,000 will develop liver cancer, and 897,000 will die from HCV-related complications.

CDC published new recommendations in August 2012 for one-time HCV testing of adults born in 1945-1965 who had no prior ascertainment of an HCV risk factor. The 1945-1965 birth cohort has a >3% prevalence of risk of infection and accounts for 3 of every 4 persons living with HCV. CDC data showed that the benefits of HCV therapy include a reduction in the risk of liver cancer by 70% and a decrease in the risk of all-cause mortality by 50%. Multiple studies and analyses that have been conducted on CDC's recommendations reported favorable cost per quality-adjusted life year.

CDC's recommendations on HCV testing of the 1945-1965 birth cohort led USPSTF to review its existing HCV testing guidelines and release the following provisional recommendations in December 2012. A Grade B recommendation (or moderate certainty that the net benefit is moderate to substantial) was made for adults at high risk of HCV (e.g., IDU history).

A Grade C recommendation (or a small benefit) was made for HCV screening and linkage to care for the 1945-1965 birth cohort. A Grade A/B recommendation was made for co-pay support performance measures and decision support. USPSTF currently is reviewing more recent data and public comments submitted on the provisional recommendations. USPSTF expects to release its final HCV testing guidelines by the end of June 2013.

Advances in HCV therapy are providing increased opportunities for clearance of viral infection, a reduction in adverse events, improved tolerability and health outcomes, and fewer of barriers to treatment. To shift from policy development to actual implementation of the recommendations in the field, efforts are underway to simplify HCV testing with easier identification of persons to test and a clearly described testing sequence. CDC released a revised HCV testing algorithm in May 2013 that recommended viremia testing of all persons with positive HCV antibody test results.

CDC launched the “No More Hepatitis” campaign with billboards, YouTube videos and other educational materials targeted to communities. CDC is collaborating with its professional organization partners to train providers in HCV testing and clinical management of chronic HCV through an online HCV course, the “Primary Care Liver Program” to link specialists and PCPs, and a series of webinars and other activities.

CDC also collaborated with its professional organization partners to convene stakeholder panels in January-March 2013 that were targeted to providers, health plans and payers, and public health. CDC will hold additional stakeholder panels in the fall of 2013 that will be targeted to other providers and states.

CDC funded a series of demonstration projects in multiple settings in FY2013 to develop strategies to implement HCV testing and linkage to care. The HHS Secretary recently announced that data collection would be extended for an additional 12 months until FY2014. CDC will evaluate data from these projects to widely disseminate best practices. The sites include:

- 10 settings for IDUs (e.g., street outreach, drug treatment programs and primary care practices) accounting for 17,900 tests;
- 7 CHCs accounting for 16,000 tests;
- 2 Project ECHO® sites (Extension for Community Healthcare Outcomes) accounting for case presentations of ~270 patients; and
- 7 HIV/STD clinics and EDs in major medical centers accounting for 15,500 tests.

Examples of the HCV testing and linkage to care demonstration projects are highlighted as follows. Grady Memorial Hospital used its funds to launch the “Trainees Identifying and Linking to Treatment for Hepatitis C” (TILT-HEPC) Project. Grady is a 1,000-bed safety net and teaching hospital in urban Atlanta that serves medically underserved populations, primarily African Americans. Medical residents were enlisted to serve as HCV screeners and seamlessly facilitate linkages to care at the Grady Liver Clinic for patients with positive HCV antibody test results. Grady has a designated CHC onsite.

Preliminary results of the TILT-HEPC Project are summarized as follows. Of 2,173 HCV antibody tests ordered to date, 1,350 HCV antibodies were drawn and 102 tests were positive

(or a 7.6% positivity rate). Of patients with positive test results, 93 were eligible for linkage to care and 79 (or 85%) kept their scheduled appointments.

The University of Alabama at Birmingham used its funds to build HCV screening capacity of ED staff for disproportionately affected populations. The existing EMR infrastructure for HIV was expanded to include a mandatory question regarding the patient's HCV testing history on the nurse triage questionnaire that is completed during the intake process.

CDC is closely collaborating with the American Medical Association Physician Consortium for Performance Improvement to establish performance standards for HCV testing and care. Existing measures regarding desired HCV outcomes, use of effective services, and patient-centered care are being updated. New measures of timely HCV care are being developed (e.g., one-time testing of the 1945-1965 birth cohort and other adults at risk, annual screening of active IDUs, and referral to treatment for patients identified with HCV). The revised and new performance standards for HCV testing and care will be submitted to NQF for adoption.

CDC is partnering with the HHS Office of the National Coordinator to explore opportunities to utilize EMRs to prompt HCV testing. Electronic specifications of clinical quality measures will be developed to monitor performance in health systems. The measures will be included in the CMS Meaningful Use Incentive Program. Clinical decision support tools (e.g., physician reminders and standing orders) will be created as companion resources to the measures.

CDC is collaborating with commercial laboratories to monitor HCV testing data. Following the publication of CDC's recommendations in August 2012, anti-HCV testing of the 1945-1965 birth cohort increased by ~16%. CDC has entered into a data sharing agreement with Quest Laboratories to obtain similar data on a quarterly basis over the next 2 years. These datasets will include provider and patient locations as well as provider specialties.

CDC used data from the National Health and Nutrition Examination Survey and an observational cohort study of >12,000 HCV patients in care to monitor the HCV test, care and cure continuum. The analysis showed that of ~3 million persons living with HCV, ~50% have been tested, 38% are in care, 23% received an HCV RNA test, 11% were treated, and 6% have achieved a sustained virologic response. CDC published its analysis in the *New England Journal of Medicine* in May 2013.

CDC's most recent surveillance data reported a 35% increase in HCV incidence in the United States in 2011 due to rise in IDU among adolescents and young adults. Dr. Thomas Frieden, Director of CDC, has identified public health/healthcare collaboration as one of CDC's key priorities for the next decade. Dr. Frieden acknowledged that robust data and measures, effective strategies to optimize the delivery of services, and a strong focus on important drivers (e.g., policy and partnership development and capacity building) will be needed to achieve this goal.

**Sanjeev Arora, MD, FACP, CHAC Member**  
Professor, Department of Internal Medicine  
University of New Mexico Health Sciences Center

Dr. Arora described HCV activities in New Mexico in his portion of the panel presentation. Estimates show that the number of persons living with HCV in New Mexico is >28,000, but <5% of these persons had been treated based on 2004 data. Of 2,300 inmates, 40% tested positive for HCV at entry to the correctional system and none had been treated. HCV is 10 times more prevalent than HIV in New Mexico.

HCV can be cured in 45%-81% of patients, but treatment is associated with anemia in 100% of cases, neutropenia in >35% of cases, and depression of >25% of cases. Moreover, no PCP in any CHC or private practice in New Mexico had ever treated an HCV patient. The waiting time for HCV patients to be treated at the University of New Mexico (UNM) Liver Clinic was eight months.

Rural New Mexico is an underserved healthcare area that covers 121,356 square miles. Of 33 counties in the state, 32 are listed as Medically Underserved Areas and 14 are designated as Health Professional Shortage areas. Of New Mexico's population of 1.83 million persons, 42.1% are Hispanic, 9.5% are Native American, and >22 lack health insurance. New Mexico's poverty rate of 17.7% exceeds the national poverty rate of 11.7%.

UNM developed Project ECHO in an effort to fill gaps in healthcare service delivery in the state. The goals of this initiative are two-fold: (1) build capacity to safely and effectively treat HCV in all areas of New Mexico and monitor outcomes and (2) develop a model to treat a complex disease in rural locations and developing countries.

Project ECHO was designed with the following methods. Technology is used (e.g., multi-point video conferencing and the Internet) to leverage scarce healthcare resources. A "Knowledge Network" is used as the platform to conduct interactive telemedicine clinics each week. A disease management model is implemented to improve health outcomes by reducing variation in processes of care and sharing best practices. HCV treatment is delivered through 21 Centers of Excellence that are housed in 16 FQHCs and 5 prisons.

Case-based learning or a "learning by doing" approach is applied for PCPs with no experience in HCV treatment to co-manage their patients with UNM specialists. PCPs who receive training under Project ECHO include physicians, mid-level providers, nurses, pharmacists and HCV educators. All Project ECHO providers receive training in using "iHealth" software. Project ECHO has shown that "learning loops" with guidance and advice from specialists, didactic presentations, and hands-on practice are extremely helpful for PCPs to rapidly become experts in HCV treatment. A web-based database that is compliant with the Health Insurance Portability and Accountability Act is used to collect data and monitor outcomes from all 21 sites.

The benefits of Project ECHO to rural clinicians include continuing medical education credits for physicians and continuing education units for nurses. Professional interaction with colleagues who have a similar interest reduces isolation and improves recruitment of patients and retention in care. Specialists in multiple disciplines are accessible, including gastroenterology, infectious diseases, hepatology, psychiatry, addiction, pharmacy and patient education.

The 2010 Arora, *et al.* study reported the HCV skills, abilities and self-efficacy of 25 community clinicians based on a scale ranging from 1 (no skills at all) to 7 (expert). The study showed that the overall competence of the clinicians greatly improved from a mean of 2.8 before participation in Project ECHO to a mean of 5.5 at the present time. Mean changes between baseline and current HCV skills, abilities and self-efficacy of the 25 clinicians in six specific areas are outlined below.

1. What is your ability to identify suitable candidates for HCV treatment? 2.8 to 5.6
2. What is your ability to assess the severity of liver disease in HCV patients? 3.2 to 5.5
3. What is your ability to treat HCV patients and manage side effects? 2.0 to 5.2
4. What is your ability to assess and manage psychiatric co-morbidities in HCV patients? 2.6 to 5.1
5. What is your ability to serve as a local consultant within your clinic and in your area for HCV questions and issues? 2.4 to 5.6
6. What is your ability to educate and motivate HCV patients? 3.0 to 5.7

UNM received federal funding to conduct an HCV trial to achieve three major objectives: (1) train PCPs in rural areas and prisons to deliver HCV treatment to rural populations of New Mexico; (2) demonstrate that the care would be as safe and effective as in a university clinic; and (3) document the ability of Project ECHO in improving access to HCV care for minorities.

The 21 Project ECHO sites served as the intervention, while the UNM Liver Clinic served as the control. The 21 Project ECHO sites were housed in 16 CHCs and 5 New Mexico prisons. Inclusion criteria were HCV cases in communities seen by PCPs and consecutive university patients. The principle endpoint was a sustained viral response or no detectable virus six months after completion of HCV treatment.

The 2011 Arora, *et al.* study reported the treatment outcomes of the HCV trial. Of 261 patients at the Project ECHO sites, 68% were minorities. The cure rates were 50% with genotype 1 and 70% with genotypes 2/3. Of 146 patients at the UNM site, 49% were minorities. The cure rates were 46% with genotype 1 and 71% with genotypes 2/3.

The study concluded that the delivery of HCV care by rural PCPs who used the Project ECHO protocol was as safe and effective as care provided in a university clinic. Project ECHO was found to improve access to HCV care for minorities in New Mexico. Treatment outcomes were

found to be better if HCV care was provided near the homes of patients in a culturally-appropriate setting with a team-based, multidisciplinary approach.

The success of Project ECHO has now been demonstrated in multiple disease areas in addition to HCV: diabetes, cardiac risk reduction, geriatrics and dementia, palliative care, rheumatology, chronic pain, integrated addiction and psychiatry, complex care, HIV, prison peer education and training, and women's health and genomics. Project ECHO has resulted in 400 points of contact across the state of New Mexico to facilitate the development of self-supporting networks. Project ECHO also has been widely replicated across the country in academic health centers, CHCs and the Veterans Administration Health System.

UNM trained the Project ECHO providers on the use of new protease inhibitors for HCV that were introduced in May 2011. Most notably, the cure rate of HCV genotype 1 increased from 40% to ~67% with Boceprevir and from 44% to 75% with Telaprevir. However, the first-generation protease inhibitors were complex, required much more system support, caused anemia and severe skin rash in ~5% of patients, and were contraindicated for an extensive list of other drugs.

New HCV drugs that are being developed are expected to resolve these problems. The four classes of drugs are nucleotide polymerase inhibitors, non-nucleotide polymerase inhibitors, protease inhibitors and NS5A replication complex inhibitors. FDA will approve a new protease inhibitor for HCV genotype 1 for use in the United States by December 2013. The drug will reduce side effects, decrease drug interactions and increase the cure rate from 70% to 80%.

FDA also will approve a new class of nucleoside/nucleotide analog polymerase inhibitors within the next six months that will be highly effective in blocking the extension process of HCV. A 90% cure rate was achieved in a cohort of 327 HCV patients with a 12-week regimen of Sofosbuvir plus Pegylated Interferon plus Ribavirin. This class of drugs will result in a shorter duration of treatment, higher cure rate, and elimination of drug resistance and toxicity.

FDA will approve an Interferon-free regimen of Sofosbuvir plus Ribavirin for use in the United States within the next six months. The 12-week regimen achieved a 97% cure rate for HCV genotype 2 in treatment-naïve patients, while the 16-week regimen achieved a 94% cure rate for HCV genotype 2 in treatment-experienced patients. The drug was not as effective for HCV genotype 3 in both treatment-naïve and treatment-experienced patients.

The 24-week regimen of Daclatasvir plus Sofosbuvir plus Ribavirin achieved a 95% cure rate in 20 HCV patients, while the 24-week regimen of Daclatasvir plus Sofosbuvir achieved a 100% cure rate in 21 patients. FDA will approve this regimen for use in the United States within the next 18 months. A four-drug combination of an oral protease inhibitor, non-nucleotide polymerase inhibitor, NS5A replication complex inhibitor and Ribavirin achieved a cure rate of ~95%.

Overall, characteristics of the new generation of direct-acting antiviral regimens will promote antiviral activity in all genotypes, provide a strong barrier to drug resistance, and result in higher cure rates and shorter duration of treatment. Oral combination regimens that are Interferon-free will have less side effects and higher cure rates. These less toxic regimens will benefit patients with cirrhosis and decompensated cirrhosis.

**Seiji Hayashi, MD, MPH, FAAFP**

Chief Medical Officer, Bureau of Primary Health Care  
Health Resources and Services Administration

Dr. Hayashi described the challenges and opportunities of integrating HIV, hepatitis and STD prevention and care in CHCs in his portion of the panel presentation. The annual patient populations of CHCs are 95,000 PLWH, 61,000 persons living with HCV, and 66,000 persons with STDs. As a federal agency, HRSA must consider five drivers that are different than those in clinical care or academia:

- development and use of policies in primary care settings to achieve an impact;
- optimal allocation of federal dollars to best support these policies;
- strategies to maximize the existing TA infrastructure at the federal level;
- indicators and data to measure effectiveness at the federal level; and
- partnerships and collaborations to improve HIV, HCV and STD prevention and care.

HRSA applies these drivers by focusing on three distinct areas. First, HRSA clearly defines specific goals to achieve. Primary, secondary and tertiary prevention of HIV, hepatitis and STD as well as care and treatment of these diseases include education, counseling, screening, behavioral interventions, immunization, and continued treatment to cure. National guidelines have been developed for all of these activities, but actual implementation in the field is difficult.

Second, HRSA identifies challenges to achieving these goals. System factors that serve as barriers include surveillance and exchange of data, workforce availability, site accessibility, coordination of and transitions in care, QI systems, and financing and coverage. Provider factors that serve as barriers include knowledge, skills, experience, tools, resources and time.

Patient factors that serve as barriers include knowledge, skills, health behaviors, preferences, competing demands, socioeconomic factors and social determinants of health. Clinical encounter factors that serve as barriers include care teams, the capture and flow of information, workflow, equipment and supplies.

In terms of provider factors, the 2003 Yarnall, *et al.* study reported that physicians would need to devote 1,773 hours per year (or 7.4 hours per working day) to fully satisfy the USPSTF guidelines for provision of preventive services. However, more recent estimates show that

physicians now need to devote ~22 hours per day to meet ~40 USPSTF A/B recommendations related to ACA, including 9 guidelines for HIV and STD screening.

HRSA's 2011 UDS data showed that hypertension (~4.3 million visits), mental illness (~4 million visits), and diabetes (~3.9 visits) accounted for the top three reasons for patient visits to CHCs. Of the top 24 categories of patient visits to CHCs in 2011, HIV/AIDS ranked 10 (413,219 visits), HCV ranked 17 (120,656 visits), syphilis and other STDs ranked 18 (109,429 visits), and hepatitis B virus (HBV) ranked 22 (21,423 visits).

National initiatives that involve CHCs and are relevant to CHAC's charter include guidelines from the *Combating the Silent Epidemic of Viral Hepatitis* Report, NHAS and ACA. HRSA is aware of the major barriers to integrating HIV, hepatitis and STD prevention and care in CHCs: a tremendous number of guidelines for providers to address in a limited amount of time; staff shortages and the need to provide assistance to existing staff; competing priorities for both providers and patients; inconsistencies between guidelines, particularly discrepancies between the CDC and USPSTF recommendations; and difficulties in collecting data and measuring progress against standard benchmarks.

Third, HRSA conducts activities to resolve challenges and take advantage of opportunities in each of the five drivers: policy, funding, TA, data/information, and partnerships/collaboration. BPHC has 5 strategic priority areas currently: All CHCs develop and fully implement their quality assurance/QI plans. EMRs are implemented across all CHC sites and providers. All CHCs will receive PCMH recognition and have met or exceeded the Healthy People 2020 goals on at least one UDS clinical measure to improve clinical outcomes. All CHCs are employers or providers of choice and support team-based care.

Because there are so many measures that could be reported HRSA is looking at composite measures to merge select UDS data and performance measures. Right now HRSA compiles measures into broad categories, such as cardiovascular and metabolic disorders, infectious diseases, respiratory diseases, perinatal health, behavioral health, oral health and cancer. Efforts also are underway to leverage partnerships to achieve mutual goals outlined in national initiatives. For example, HRSA and SAMHSA could use NHAS in a joint effort to achieve a greater collective impact on HIV/AIDS, substance abuse and mental illness.

Despite these ongoing efforts, HRSA is aware that more systems and process improvements are still needed in CHCs. Point-of-care decision support tools include risk identification, clinical decision support, automation, service packaging and prioritization. Tele-health technology includes remote monitoring and care, such as Project ECHO. Workforce redesign includes team-based care and specialty partnership models.

Workflow redesign includes team-based care, enhanced self-care and community-based care. Learning systems include collaboratives, data warehousing and benchmarking, best practices,

case studies and implementation toolkits. Dr. Hayashi asked CHAC to identify and prioritize other actions that would be most effective in integrating HIV, hepatitis and STD prevention and care in CHCs.

CHAC discussed the following topics in the question/answer session with Drs. Ward, Arora and Hayashi on the challenges and opportunities in the test and cure era for HCV.

- Geographic variations in access to HCV care and treatment in the United States (e.g., a rural community versus a state with a “medically underserved” designation).
- The absence of national HCV initiatives in correctional settings.
- The inability of private practices to administer expensive HCV drugs to patients.
- Ongoing efforts to increase the focus on sexually-transmitted HCV, particularly in the population of HIV-positive MSM.

### **Panel Discussion: Implementation of Clinical Preventive Services in CHCs**

#### **John Douglas, Jr., MD**

Chief Medical Officer, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention  
CHAC Designated Federal Officer, CDC

#### **Advice Requested from CHAC by CDC and HRSA:**

- What are the best strategies for PCPs in typical CHCs to address STD and HIV clinical preventive services?
- What are the challenges that prevent CHCs from providing recommended services? What are the best strategies to address these challenges?
- What are the best strategies for PCMHs to establish and institutionalize ongoing, coordinated screening practices?
- What are the best strategies to coordinate these and related recommended services (e.g., HIV and HBV testing and HBV and HPV immunization) with other CHC priorities? What specific priorities should be viewed as less critical? What approach should CHCs and PCPs utilize to guide the decision-making process?
- What assistance can CDC and HRSA give to help CHCs and PCPs provide these services in a manner that is consistent with high-quality STD/HCV preventive care?

Dr. Douglas moderated a panel discussion with the presenters from the STD and HCV panels. However, he asked the participants to join him in welcoming Dr. Hogai Nassery who would serve as an additional panelist. Dr. Nassery is the Deputy Vice President of Ambulatory and Community Medicine and Chief of the Community Medicine Division at Grady Health System in Atlanta.

Dr. Douglas began the panel discussion by asking the panelists to describe key issues that CHAC should consider in formulating recommendations/resolutions on integrating HIV, HCV, STD and other related clinical preventive services in CHCs.

**Dr. Seiji Hayashi:** CHAC's guidance should focus on the best strategies to organize and package the delivery of HIV, HCV and STD services in CHCs. For example, HIV and HCV testing could be easily performed simultaneously, but STD testing could be conducted at the same visit as well. Sexual health also should be included in this package of services due to its broader focus beyond infectious diseases and its inclusion of the entire CHC patient population. A team-based care model that includes patients should be implemented because PCPs cannot be solely responsible for performing these services. For example, a member of the team other than the physician might have more expertise and time in providing counseling to patients.

**Dr. Hogai Nassery:** Unlike public health, PCPs typically do not make a distinction between "sexual health" and "overall health." If depression and behavioral health issues are addressed during each routine visit, for example, a greater impact can be achieved in patient compliance and a reduction in risky sexual behaviors.

In terms of task shifting, peer counselors and peer navigators are extremely helpful and cost-effective in a team-based care model. Antibody, reflex and confirmatory testing should be performed in one visit to expedite diagnosis and treatment and also to decrease barriers to patients presenting for follow-up and referral. PCPs can easily screen for and diagnose HIV, HCV and STDs, but treatment of these diseases would be extremely problematic in some primary care settings, particularly small practices.

**Dr. Daniel Miller:** PCPs consider prevention by age groups (e.g., children, adolescents, young adults and seniors), while public health views prevention by disease groups (e.g., HIV, hepatitis and STDs). PCPs also focus on specific populations in terms of sexuality and screening of certain conditions and diseases.

HRHCare transformed to a PCMH model by first determining all tasks that should be performed before, during and after a patient visit and then identifying staff with expertise for each job description. This exercise showed tremendous overlap in some areas and gaps in others. For example, a member of the team other than the clinician should order a chlamydia test based on an alert in the patient's EMR and take all necessary follow-up actions. Stronger efforts must be made to target and reach persons with the greatest need for assistance and care from CHCs, but who have no access to these services.

**Dr. David Stevens:** PCPs should integrate prevention and care services based on patient age groups that have been formally established: prenatal, childhood, adolescent, adult and geriatric care. PCPs also should expand the traditional medical history to include psychosocial risks and

healthcare system issues (e.g., specific reasons for patients missing an appointment with a recommended specialist and follow-up to confirm that patients were notified of their test results). The PCMH model should include an extensive staff engagement component to provide training on cultural issues. This approach would help CHCs to better understand and serve various types of patients (e.g., vulnerable, hard-to-reach, disenfranchised or underserved patients).

CHAC agreed that the important and timely topic of integrating HIV, HCV, STD and other related clinical preventive services in CHCs warranted a formal recommendation or resolution to the CDC Director, HRSA Administrator and/or HHS Secretary. The members suggested a number of issues that should be considered in drafting the language.

- CHAC should advise the federal agencies to give more attention, funding and support to training programs targeted to non-clinical staff in CHCs. For example, CHC staff other than clinicians should be trained to conduct prevention visits with patients that would be separate from their routine medical visits with physicians. Experienced providers in CHCs rather than experts in specialized HIV or hepatitis clinics should be designated to administer ART to HIV patients or give new drug regimens to HCV patients. A reimbursement system should be established as an incentive for CHCs to provide these integrated services.
- CHAC's guidance to the federal agencies should be worded to address the tremendous administrative barriers to integrating prevention and care across infectious diseases.
- CHAC should formulate guidance to the federal agencies based on four major areas that are essential to integrated services and will require a multidisciplinary team of providers both inside and outside of CHCs: assessment, testing, treatment, and prevention with positives (*i.e.*, care). CHAC also should advise the federal agencies to invest in a task-shifting or team-based care model based on answers to the following questions:
  - Who is responsible for each of these four areas?
  - Who has sufficient time to perform tasks in each of these four areas?
  - Who will be paid under ACA for providing these services?
- CHAC should advise the federal agencies to incorporate HIV, HCV and STD testing into EMRs and provide incentives for achieving these prevention goals. This strategy could improve compliance with national guidelines and enhance delivery of care, but rigorous indicators would need to be developed to measure effectiveness. This approach should be modeled after incentives the federal government awards to agencies for their success in meeting Meaningful Use measures.
- CHAC should advise HHS to designate a small group of CMMI demonstration projects to document whether new healthcare systems have the capacity to identify more patients who are at risk for HIV, HCV or STDs and facilitate more treatment and follow-up.
- CHAC should advise the federal agencies to foster partnerships among experienced providers in CHCs, infectious disease experts in specialty clinics and public health agencies to collect and maintain data. This approach ideally would provide clinicians

and care teams with access to local epidemiologic data to better inform the development and monitoring of local systems.

- CHAC's guidance to the federal agencies should explore the possibility of expanding the existing "medically underserved" designation. The definition does not allow CHCs to fully address health disparities in racial/ethnic minority and sexual minority groups. For example, CHCs could train staff to focus a portion of their clinical operations on hard-to-reach, vulnerable and other special populations (e.g., homeless persons, IDUs and the LGBT community). This approach could improve provider-patient interactions and achieve a greater impact in health outcomes.
- CHAC's guidance to the federal agencies should describe strategies to link the strengths of existing systems. For example, CMMI grants for QI and payment models should be replicated to demonstrate linkages between the expertise of CHCs and HIV, HCV and STD specialists. Innovation grants also should be awarded to demonstrate the capacity of CHCs, hospitals and health departments in seamlessly facilitating the continuum of care, data exchange and ongoing management of HIV and HCV patients.
- HRSA should encourage CHCs to institutionalize a simultaneous clinical management, administrative management and continuous QI approach to assist both clinical and non-clinical staff in improving performance in patient retention, clinical outcomes and overall quality of care.
- CHCs should be closely involved in conducting community assessments to determine the local incidence and prevalence of HIV, hepatitis and STDs. This approach would help CHCs in prioritizing funding and activities based on local needs and identifying subgroups in communities that have the highest need for prevention, care and treatment services.
- HSRA should administer a survey to CHCs to determine whether written consent from each patient is required for HIV testing in their particular state. This law serves as a barrier to providers complying with HIV testing recommendations, but some states do not require written consent.

Dr. Arora announced that he would be unable to attend the remainder of the meeting. He proposed an "integration" recommendation for CHAC's formal vote during the business session on the following day, but he noted that the draft language was specific to hepatitis only. In his absence, he asked his CHAC colleagues to modify, refine and expand the recommendation to include the integration of HIV, STD and other related clinical preventive services in primary care settings.

A new disease was discovered in 1989 and the death rate continues to rise. The disease occurred at a time and in a population with minimal advocacy, but curative treatment now exists to potentially save thousands of lives. No system has been engineered to address this problem to date, but primary care is the appropriate setting.

- CHAC recommends that HHS initiate a process to determine the optimal strategy to resolve this problem at both primary care and federal government levels.
- CHAC recommends that HHS initiate a process to determine the optimal task-shifting strategy for medical assistants, peer educators, community health workers and nurses to be responsible for the multitude of tasks in emerging new mandates.
- CHAC recommends that HHS initiate a process to clearly describe different duties of various healthcare personnel.
- CHAC recommends that HHS identify payment mechanisms to actually implement the new system in the field.

## Overview of the HIV Medical Monitoring Project (MMP)

### Jacek Skarbinski, MD

Clinical Outcomes Team Lead, NCHHSTP Behavioral and Clinical Surveillance Branch  
Centers for Disease Control and Prevention

Dr. Skarbinski presented an overview of MMP. MMP is a supplemental surveillance system that CDC created in 2005 in response to the 2004 IOM Report, *Measuring What Matters: Allocation, Planning and Quality Assessment for the Ryan White Care Act*. The IOM report emphasized the need for population-based, nationally representative data on HIV-infected persons in care.

CDC designed MMP to monitor HIV care in the United States in three broad categories: (1) administration of ART with a goal of achieving viral suppression; (2) implementation of other interventions to reduce transmission-based HIV risks (e.g., screening and treatment of STDs, behavioral interventions, condom distribution, decreased substance abuse, and reduction of other known co-morbidities leading to HIV transmission); and (3) management of all other co-morbidities, including AIDS and non-AIDS defining conditions.

The overarching purpose of MMP is to better understand the delivery of HIV care at the broadest level and make significant contributions to achieving the three NHAS goals for HIV care and treatment: reduce new infections, decrease disparities and improve health outcomes. The secondary function of MMP is to collect and maintain data on financing and organizing the delivery of HIV care.

CDC designed MMP as a three-stage complex sample and cross-sectional survey. In stage 1, data are collected from all 50 U.S. states, the District of Columbia and Puerto Rico to obtain a sample of HIV-infected persons in care in 17 states or territories. The stage 1 cohort represents 73% of all adults diagnosed with HIV in the United States. In stage 2, outpatient HIV care facilities are sampled from the stage 1 states or territories. In stage 3, HIV-infected adults who

received at least one medical care visit from January to April are sampled from the stage 2 facilities.

The 23 sites that currently receive MMP funding for the 2009-2014 project period include 16 U.S. states, Puerto Rico, and 6 independently funded public health jurisdictions within the sampled states. CDC collects MMP data from face-to-face interviews that include self-reported demographics, experiences and behaviors of patients; information from medical record abstractions (MRAs) of documented clinical care, ART prescriptions and viral suppression; data reported to the CDC National HIV Surveillance System; HIV provider surveys administered to MMP-funded facilities; and facility characteristics.

MMP has achieved tremendous growth since its establishment in 2005: an increase in the number of participating project areas from 10 in 2005 to 23 in 2012; an increase in the number of participating facilities from 107 in 2005 to 473 in 2012; an increase in the number of interviews from 900 in 2005 to 5,153 in 2012; and an increase in the number of MRAs from 4,787 in 2007 to 6,410 in 2012. MMP response rates also have increased from 70%-85% by facility, 41%-55% by interview, and 29%-47% overall.

The White House Office of National AIDS Policy (ONAP) commissioned IOM to produce guidance on monitoring care for PLWH in the United States. The first IOM report in March 2012 included recommendations on indicators and data systems, while the second IOM report in October 2012 included recommendations to generate national estimates of HIV care and coverage. The second IOM report highlighted MMP as a potential data source in this regard and targeted specific guidance to CDC.

CDC's actions to respond to the IOM recommendations in the second report are outlined as follows. IOM recommendation 2 advised CDC to improve MMP by 2015 to ensure higher response rates and increase the representation of samples by including the following vulnerable populations in the surveillance system: HIV-diagnosed persons not in care, HIV-diagnosed adolescents, persons in the criminal justice system, immigrants, homeless and/or unstably housed persons, and individuals with mental or substance use disorders.

To increase facility and patient participation in MMP, CDC has made efforts in several areas over the past two years:

- simplified data collection procedures;
- provided additional supervision for MMP project areas with poor performance;
- established a peer-to-peer mentoring program to share best practices;
- modified facility sampling procedures to reduce the number of low-volume facilities sampled;
- increased engagement with members of the MMP Provider Advisory Board (PAB) and Community Advisory Board (CAB);

- enhanced facility and patient incentives as appropriate;
- improved national- and local-level awareness of MMP; and
- implemented telephone interviewing as an additional data collection methods

To expand MMP to include representative numbers of HIV-diagnosed persons not in care, CDC is piloting the Case Surveillance-Based Sampling (CSBS) project. CDC designed CSBS to use HIV case surveillance as the sampling frame to expand the MMP population of inference to include HIV-diagnosed persons who are both in and out of care. The goals of CSBS are to assess the feasibility of implementing this strategy, develop methods to locate and contact sampled persons, collect data, and perform sampling and weighting. The two-year pilot project will be conducted from June 2012 to June 2014 in Los Angeles County, Mississippi, New York City, San Francisco and Washington State.

To expand MMP to include representative numbers of HIV-diagnosed adolescents and persons in the criminal justice system, CDC would need to collect data from MMP on a few persons per data collection cycle. CDC acknowledges that these subpopulations are very important, but are extremely small in size to make estimates. Because <1% of HIV-diagnosed persons are adolescents, for example, MMP would collect data on only ~20 adolescents per data collection cycle.

Moreover, the inclusion of these small vulnerable subpopulations will be problematic from an operational perspective. The addition of more regulatory processes will affect response rates and data collection operations will be more complex. CDC is proposing an alternative to respond to this recommendation without expanding the scope of MMP. MMP data collection will be customized and focused on the specific needs of adolescents and persons in the criminal justice system.

To ensure adequate representation of other vulnerable populations (e.g., immigrants, homeless and/or unstably housed persons, and individuals with mental or substance use disorders), CDC has reviewed its existing MMP data and confirmed that these groups most likely are not underrepresented. Based on 2009 data, the MMP population includes immigrants (13%), homeless persons (9%), non-IDUs (27%) and persons with depression (26%). These percentages are within the expected range for HIV-infected adults who receive medical care.

IOM recommendation 3 advised ONAP and HHS to use the improved version of MMP to obtain nationally representative data on healthcare coverage and utilization for PLWH. Since the 2009 data collection cycle, MMP has the capacity to produce nationally representative estimates of key indicators. However, CDC is continuing to make incremental improvements in MMP and also is actively assessing the feasibility of sampling from case surveillance to expand the reference population.

IOM recommendation 4 advised HHS to convene and fund a multidisciplinary task force that would be responsible for designing improvements to MMP and ensuring its continued

responsiveness to changes in the HIV epidemic and healthcare environment over time. CDC has increased its engagement with CABs and PABs that have been established in all 23 MMP project areas with diverse memberships, including CDC, HRSA, professional associations, AETCs and multiple CBOs. However, CDC is proposing to use CHAC as an additional resource to guide further improvements to MMP.

IOM recommendation 7 advised HHS to produce and disseminate a report at least once every two years on the care of PLWH. IOM noted that each report should characterize trends and identify gaps in coverage and care during and following the implementation of ACA. CDC agrees with and will make efforts to address this recommendation.

In addition to improving MMP to respond to the IOM recommendations, CDC also is determining the role of MMP in monitoring ACA in three distinct areas: (1) making population-based estimates of persons who are diagnosed with HIV and retained in care; (2) estimating health insurance and other coverage among HIV-infected adults who receive medical care; and (3) better understanding the contributions of RWP funding to the delivery of HIV care.

The 2013 Hall, *et al.* study reported on the percentage of HIV-diagnosed persons at specific stages along the continuum of care, including those who are retained in care, prescribed ART and virally suppressed. The 2013 Quinn and Skarbinski abstract estimated that of all HIV-infected adults in care, 83% have some type of health insurance, 13% have RWP coverage only, and 4% have no documented payer source. The 6 types of health insurance or coverage for this population are Medicaid (42%), RWP (39%), private insurance (32%), Medicare (27%), other public insurance (5%), and military insurance (2%).

CDC performed modeling with MMP data to determine the association between health insurance or coverage and viral suppression. The percentage of HIV-infected adults in care who achieved viral suppression ranged from 56% with other public insurance to 81% with military insurance. Medicaid recipients were significantly less likely to achieve viral suppression compared to all other coverage types, while persons with private insurance, Medicare and military insurance were significantly more likely to achieve viral suppression.

Age, race/ethnicity, poverty, homelessness, foreign-born status, time since diagnosis and stage of disease were independently associated with viral suppression. After the models were adjusted for these covariates, persons with other public insurance were significantly less likely to achieve viral suppression compared to all other coverage types, while persons with Medicare and military insurance were significantly more likely to achieve viral suppression. Persons with Medicaid, RWP funding and private insurance were equally likely to achieve viral suppression.

CDC is performing additional modeling with MMP data to determine the potential impact of ACA on health insurance coverage for HIV-infected adults in care. Poverty level is included in these models to assess the potential impact of ACA on the number of HIV-infected adults who receive

medical care and are eligible for Medicaid after expansion and health insurance marketplaces, including subsidies.

The 2012 Weiser, *et al.* study reported that 33% of outpatient HIV facilities receive RWP funding and 69% of HIV-infected persons who receive medical care attend RWP-funded facilities. Patients who receive care at RWP-funded facilities are significantly more likely to be younger, African American or Hispanic, heterosexual, less educated, lower income and homeless.

Based on 2009 MMP data, RWP-funded facilities were significantly more likely than non-RWP-funded facilities to provide onsite support services to HIV-infected persons. These services include case management, substance abuse treatment, mental health services, social services, dental services, adherence counseling, nutrition counseling, language translation and risk reduction counseling.

HIV-infected patients who attend RWP-funded facilities were significantly more likely to report needing and receiving support services. CDC will use MMP data to assess the quality of care at RWP-funded facilities to determine whether this patient population is more or less likely to achieve viral suppression.

Overall, MMP is a unique surveillance system that is designed to monitor HIV care in the United States and provide nationally representative population-based and prevalence estimates. The rich MMP dataset is linked to interviews, MRAs and facility attributes. MMP can be used to guide national and local HIV prevention and treatment efforts.

**Jennifer Kates, PhD, CHAC Member**

Vice President & Director, Global Health and HIV Policy  
Kaiser Family Foundation

Dr. Kates co-chairs the CHAC Data Workgroup and was a member of the IOM committee that made the recommendations related to MMP. The position of the IOM committee was that MMP was the most promising mechanism to provide ongoing policy, clinical and other quality data to evaluate access to care among PLWH in the United States. The Data Workgroup will continue to review MMP and other CDC and HRSA datasets to inform the development of guidance that will be presented to CHAC in the future.

Dr. Kates commended CDC for its tremendous and rapid progress in improving MMP, particularly since the IOM report was only released eight months ago in October 2012. She noted that MMP would be an extremely valuable resource in learning about the health outcomes of PLWH as changes are made to the existing care delivery system.

CHAC discussed the following topics in the question/answer session with Dr. Skarbinski on MMP.

- The possibility of comparing two funding streams (e.g., insurance exchanges/Medicaid expansion versus RWP funding) that will be available for direct medical services for PLWH.
- The ability of MMP to capture and represent HIV-positive Native Americans who receive care from Indian Health Service, Native American/Alaska Native or tribal clinics.
- The need for CDC to stratify MMP data to estimate the proportion of PLWH who achieved viral suppression by race/ethnicity plus insurance type and by geographic location.

## Public Comment Session

### **Chris Taylor**

Associate Director for Viral Hepatitis  
National Alliance of State and Territorial AIDS Directors

Mr. Taylor made the following comments for CHAC's consideration. CHAC should ensure that its resolutions/recommendations related to viral hepatitis are forwarded to the HHS agencies with responsibility for renewing the National Viral Hepatitis Action Plan (VHAP). Lessons learned and best practices of HIV, hepatitis and STD programs that are housed in state and local health departments and have strong relationships with CHCs should be compiled and disseminated. Efforts should be made to identify gaps in traditional safety net programs and wraparound services in state and local health departments as ACA is implemented over time.

### **Carole Treston, RN, MPH**

Policy and Advocacy Consultant  
Association of Nurses in AIDS Care

Ms. Treston made the following comments for CHAC's consideration. CHAC should thoroughly consider the role of mid-level nurses and nurse practitioners when formulating guidance on task shifting. However, issues related to licensure and scope of practice will need to be resolved in order to maximize the role of nurses in task shifting and fill gaps in PCP shortages. Although scope of practice is a state issue, CHAC's recommendations to federal agencies can still have an impact at the state level. For example, state nursing organizations can formally adopt and institutionalize a CHAC resolution/recommendation to expand the scope of practice for nurses.

## Preparation for the CHAC Business Session

### **Antigone Dempsey MEd, CHAC co-Chair**

Deputy Director, Knowledge, Transfer and Technical Assistance  
HIV/AIDS Lead, Altarum Institute

Ms. Dempsey described the organizational structure of CHAC meetings in addition to the business session process for the benefit of the new members. CDC and HRSA sponsor two CHAC meetings per year: a CDC-focused meeting in late spring/early summer and a HRSA-focused meeting in late fall/early winter. However, all meetings are designed for CHAC to discuss and provide advice to both agencies on cross-cutting issues.

The CHAC co-Chairs and the CDC/HRSA Designated Federal Officers (DFOs) hold a series of conference calls after each meeting to plan for the next meeting. The co-Chairs and DFOs develop future agendas based on priority issues for the agencies and topics of interest identified by individual CHAC members. Beginning with the May 2012 meeting, CHAC's organizational structure was changed to shorten presentations and provide an opportunity for the members to have more substantive and interactive discussions with the federal agencies, guest speakers and members of the public.

The business session is devoted to CHAC proposing recommendations/resolutions for formal votes, suggesting agenda items for future meetings, and reviewing action items or next steps for CHAC, CDC and HRSA. A "recommendation" is defined as CHAC's request for the HHS Secretary, CDC Director and/or HRSA Administrator to take specific action on a particular topic. A "resolution" is defined as CHAC's formal statement or position on a particular topic that will be on record with the HHS Secretary, CDC Director and/or HRSA Administrator.

CHAC was given a 2-page document during the May 2012 meeting that provided clear guidance on making resolutions/recommendations, described issues the voting members should consider in proposing recommendations/resolutions, and defined the role of Federal Advisory Committee workgroups. Ms. Dempsey confirmed that the 2-page guidance document would be provided to the new CHAC members. In the interim, she encouraged the new members to review the December 2012 CHAC meeting minutes to better understand the business session process.

To ensure ongoing quality improvement of CHAC's organizational structure and advisory role, Ms. Dempsey asked the entire membership to target, focus and streamline its guidance with fewer recommendations/resolutions that would be more meaningful and strategic. For example, the 8 recommendations/resolutions that CHAC unanimously approved during the December 2012 meeting could be extremely burdensome for CHAC, CDC and HRSA to take action on and monitor progress over time.

Ms. Dempsey announced that another component of CHAC's new organizational structure has been the assignment of "champions" to take the lead in drafting the language and spearheading support for each proposed resolution or recommendation. This approach has been extremely effective over the past year, particularly for recommendations that warrant the formation of a new CHAC workgroup. Most notably, the series of letters signed by the HHS Secretary, CDC Director and/or HRSA Administrator following the December 2012 meeting has been the most rapid and highest degree of response that CHAC has received from the federal agencies on its formally approved recommendations.

Ms. Dempsey emphasized that due to severe cuts in federal budgets, the level of CDC and HRSA funding and support for CHAC workgroups and other activities outside of public meetings is limited. As a result, the champions and their CHAC colleagues must take leadership and ownership of each recommendation in terms of convening teleconferences with workgroup members, monitoring progress and ensuring accountability.

Ms. Dempsey led CHAC in a review of topics from the presentations and panel discussions on day 1 that would be proposed for a formal vote during the business session on the following day. The CHAC members also described specific issues that the champions should consider in drafting recommendations/resolutions for these topics.

Topic 1: Optimal strategies for the integration of HIV, HCV and STD prevention and care in primary care settings

Champions: Sanjeev Arora, MD, FACP; Kathleen Clanon, MD; Dawn Fukuda, ScM

- Strategies to link or "bundle" the strengths of various systems to promote the creation of integrated measures, training, QI initiatives, or EMR-based clinical decision support packages in primary care settings
- Task shifting
- More effective use of resources and the development of strategies to take advantage of changes in health reform and system reform to build a new and integrated primary care model in the United States
- Improvement of health outcomes for patients
- Administrative barriers to integration of HIV, HCV and STD services in primary care settings
- Reimbursement mechanisms, including payment for nursing services
- Provider expertise

Topic 2: Establishment of a new "Integration Workgroup"

Champions: Kali Lindsey; Antigone Dempsey, MEd

- A clearly defined charge, purpose, goals and activities of the new workgroup:

- Emphasis on primary care across programs and disease areas at federal, state and/or local levels
- Review and expansion of the CDC Program Collaboration and Service Integration initiative, including the evidence base, best practices and other key outcomes from this effort

Topic 3: Performance measures

Champion: Jeanne Marrazzo, MD, MPH

- The need for HAB to develop broader performance measures beyond HIV (e.g., detection and treatment of STDs in HIV care settings and other prevention, treatment and care measures that are priorities for CHAC)
- Identification of clinically meaningful indicators to validate, track and monitor the impact of measures for both performance and payment

Topic 4: CDC/HRSA-Ryan White Funding

Champions: Dawn Fukuda, ScM; Angelique Croasdale, MA; Jennifer Kates, PhD; Jeanne Marrazzo, MD, MPH

- Loss of HIV, viral hepatitis and STD activities if CDC prevention dollars and/or HRSA/Ryan White funding were removed from the existing system
- The need for an analysis to determine the ability of health insurance plans and third-party reimbursement mechanisms to readily replace federal investments that are targeted to HIV, viral hepatitis and STD activities, infrastructure and outcomes

Topic 5: Community health assessments

Champions: Antigone Dempsey, MEd; Bruce Agins, MD, MPH

- Collection of data from local community health assessments to inform preventive care and treatment in primary care settings

With no further discussion or business brought before CHAC, Ms. Dempsey recessed the meeting at 4:37 p.m. on June 18, 2012.

**Opening Session: June 19, 2013**

**John Douglas, Jr., MD**

Chief Medical Officer, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention  
CHAC Designated Federal Officer, CDC

Dr. Douglas conducted a roll call to determine the CHAC voting members, *ex-officio* members and liaison representatives who were in attendance. None of the voting members publicly disclosed any individual or institutional conflicts of interest for the record that were new or different than those declared on day 1 of the meeting.

Dr. Douglas verified that the voting members and *ex-officio* members constituted a quorum for CHAC to conduct its business on June 19, 2013. He reconvened the proceedings at 8:43 a.m. and welcomed the participants to day 2 of the CHAC meeting.

Dr. Douglas announced that CHAC meetings are open to the public and all comments made during the proceedings are a matter of public record. He reminded the CHAC voting members of their individual responsibility to identify real or perceived conflicts of interest and recuse themselves from participating in these matters.

**Antigone Dempsey MEd, CHAC co-Chair**

Deputy Director, Knowledge, Transfer and Technical Assistance  
HIV/AIDS Lead, Altarum Institute

Ms. Dempsey emphasized that the voices and experiences of persons who have the greatest need to access HIV, hepatitis and STD services were not reflected in the discussions on the previous day. Most notably, vulnerable populations typically mistrust the medical system because traditional providers with no cultural competence often view these persons with disdain. CHAC's guidance should emphasize the need for training, education and assistance to vulnerable populations to promote self-efficacy for their individual care.

**Jeanne Marrazzo, MD, MPH, CHAC co-Chair**

Professor of Medicine, Harborview Medical Center  
University of Washington

Dr. Marrazzo agreed that CHAC's guidance should be extremely respectful to its target patient populations. The HIV, hepatitis and STD prevention and care systems are intimidating and complex even for well educated persons who need these services. The panel presentations and discussions on the previous day reflected tremendous advancements and progress from the previous reluctance of CHCs to conduct routine HIV testing.

## Draft Recommendations for HIV Diagnostic Laboratory Testing

### **Bernard Branson, MD**

Associate Director for Laboratory Diagnostics  
Division of HIV/AIDS Prevention  
Centers for Disease Control and Prevention

#### **Advice Requested from CHAC by DHAP:**

- What are CHAC's comments or suggestions on changes to the draft recommendations?
- What are the best strategies to educate care providers and the public on the new HIV diagnostic sequence?
- What are the potential logistical barriers to adoption of the new testing algorithm?

Dr. Branson presented updated recommendations and a new algorithm for diagnostic laboratory testing of HIV infection. HIV tests have greatly evolved over time since the introduction of first-generation confirmatory tests in 1985 to the introduction of the “combo” antigen/antibody enzyme immunoassay (EIA) in 2011.

First-generation tests were made of whole viral lysate and second-generation tests were made of synthetic peptides. Both first- and second-generation tests detected immunoglobulin G (IgG) antibodies only. Third-generation tests detected both IgG and immunoglobulin M (IgM) antibodies, while fourth-generation tests detect IgG and IgM antibodies in addition to p24 antigen. Nucleic acid tests (NATs) detect HIV RNA, “combi” tests detect both HIV-1 and HIV-2 antibodies, and “combo” tests detect antigen and antibodies.

Based on laboratory markers, HIV infection occurs at day 0 followed by the appearance of HIV RNA in plasma, HIV p24 antigen and HIV antibody. First-generation tests detected HIV at ~50-60 days after the time of infection. Second- and third-generation tests improved sensitivity to detect HIV infection earlier, while fourth-generation tests shortened the interval between the appearance of HIV RNA in plasma and detection of HIV infection to ~5 days.

The 2005 Cohen, *et al.* study reported on the increased risk of sexual transmission of HIV during acute infection. The likelihood of transmission of infection during the acute phase is 10-100 times higher than the asymptomatic phase. HIV virus that is successfully transmitted is 75-750 times more infectious than HIV virus in long-term infection.

CDC conducted studies on seroconversion panels of all HIV tests that currently are approved by FDA. With 166 specimens from 17 seroconverters, CDC calculated the cumulative frequency when each test detected HIV in 50% of seroconverter specimens, compared with when the Western blot became positive. The Western blot algorithm turned positive at approximately the same time as the Vironostika, but later than all other assays currently on the market in the U.S.

The Vironostka test was used by 66% of all public health laboratories and both commercial laboratories until its withdrawal from the market in 2007. As a result, evaluations of the performance of other HIV tests on the market used the Western blot and Vironostka tests as the standard.

The Aptima qualitative test detects HIV RNA ~26 days before the Western blot turns positive. Current lateral flow rapid tests that are waived by Clinical Laboratory Improvement Amendments detect HIV infection ~1-5 days before the Western blot turns positive. The Multi-Spot, Reveal and the newest lateral flow tests as well as the second-generation EIA detect HIV infection ~1 week before the Western blot turns positive.

Third-generation antibody tests that currently are used by most public health laboratories detect HIV infection ~2 weeks before the Western blot turns positive. Fourth-generation tests shorten this interval by ~5-7 days and increasingly are being adopted across the country by public health, hospital and clinical laboratories. FDA currently is considering the approval of a fourth-generation rapid test that is an antigen/antibody combination. All HIV screening tests in current use can detect HIV infection before the Western blot, but laboratories are still advised to apply the algorithm of using the Western blot to confirm a positive HIV test result. The HIV status of some individuals has been incorrectly classified due to discordant results in this algorithm.

Limitations of the Western blot algorithm include the inability of antibody tests to detect infection in ~10% of HIV-infected persons at highest risk of transmission, particularly MSM. Western blot confirmation is less sensitive during early infection than many screening tests that are widely used. Inherent delays caused by centralized screening reduce the effective sensitivity because HIV-infected persons do not immediately learn their test results.

HIV-2 infection remains uncommon in the United States and cannot be detected by HIV-1 viral load tests. HIV-2 infection does not respond to non-nucleoside reverse transcriptase inhibitors and some protease inhibitors. The 2010 Torian, *et al.* study and a July 2011 article published in the *Morbidity and Mortality Weekly Report (MMWR)* showed that 93% of HIV-2 patients tested in New York City had a positive HIV-1 Western blot and 60% of HIV-2 cases reported to CDC had a positive HIV-1 Western blot. HIV-2 often is diagnosed after immunologic deterioration in patients with a negative viral load.

In an effort to resolve these problems, CDC developed a new HIV testing algorithm with a fourth-generation HIV-1/2 antigen/antibody combination immunoassay for primary screening in laboratories. An HIV-1/HIV-2 antibody differentiation immunoassay will be performed if the test is positive. The first two tests will identify the majority of persons who have HIV infection at the time of testing and are antibody-positive. Persons who are detected with positive HIV-1 and HIV-2 antibody test results will be referred to care, but additional testing also will be conducted to rule out dual infection. NAT will be performed for negative or indeterminate HIV-1 or HIV-2

antibody test results. This sequence of tests is CDC's preferred algorithm that will be used to test serum or plasma.

Public health and clinical laboratories that CDC engaged to evaluate the performance of the new immunoassay found the algorithm to be equivalent to the Western blot in identifying longstanding infections. The laboratories also determined that the algorithm had the ability to detect more acute HIV infections earlier with fewer indeterminate results for antibody-positive persons at a faster turnaround time for test results. CDC's cost analysis studies showed that the cost of the new algorithm was equal to or lower than current practice.

CDC will publish an *MMWR* article in the near future highlighting evaluation results of the use of the new algorithm in an ED and a multi-site study. In both cases, the algorithm identified a considerable number of acute HIV infections that would have been reported as "uninfected" based on the Western blot.

CDC drafted the following recommendations following multiple laboratory evaluations. Screening should be initiated with the fourth-generation antigen/antibody combination immunoassay. Reactive specimens should be tested with an antibody assay that differentiates between HIV-1 and HIV-2 antibodies to overcome misclassification problems with the Western blot. Persons with reactive specimens on the initial immunoassay and antibody differentiation immunoassay should be considered positive for HIV-1 or HIV-2 antibodies and referred to medical care and laboratory testing, including viral load, CD4 and antiretroviral resistance assays.

Specimens that are reactive on the initial immunoassay and negative on the HIV-1/HIV-2 antibody differentiation immunoassay should be tested for HIV-1 RNA. A reactive result should be interpreted as acute HIV-1 infection. Beginning with the fourth-generation immunoassay, the same testing algorithm should be followed for specimens with a previous reactive rapid HIV test result.

In addition to its draft recommendations, CDC also proposed alternatives because most HIV tests that currently are on the market are in different classes. Each of these alternatives, however, has limitations compared with the preferred algorithm. If a third-generation HIV-1/2 immunoassay is used as the initial test, subsequent testing specified in the algorithm should be performed.

If an alternative second-generation antibody test is used (e.g., immunofluorescence assay or Western blot as the 2<sup>nd</sup> test in the algorithm), an HIV-1 NAT should be performed on specimens with negative or indeterminate test results and an HIV-2 antibody immunoassay should be performed on specimens with negative HIV-1 NAT results. If an HIV-1 NAT is used as the second test and is positive, the specimen should be classified as positive for HIV-1 infection.

The HIV-1/HIV-2 antibody differentiation assay should be performed if the test result is negative. This alternative will not differentiate acute from established HIV-1 infection.

In terms of reporting, clinical laboratories can report the result of each test in the sequence as it becomes available. Reporting language should accompany test results to ensure accurate interpretation by clinicians. Laboratories should coordinate reporting of results with surveillance programs to ensure accurate interpretation. CDC will collaborate with the Association of Public Health Laboratories to develop the reporting language.

The draft recommendations supersede CDC's guidelines and protocols for use of the Western blot algorithm (1989), HIV-2 antibody testing (1992), and confirmation of reactive rapid tests (2004). The new algorithm screens for both virologic and serologic markers of HIV infection, incorporates NAT to resolve discordant immunoassay results, identifies acute HIV-1 infection, and reduces indeterminate test results. Moreover, all immunoassay-positive specimens are tested for HIV-2 for prompt identification.

The new algorithm emphasizes sensitivity during both initial and follow-up testing, but rare false-positive antibody test results can still occur. However, false-positive results would be discovered during subsequent laboratory testing that is recommended as part of the initial clinical evaluation. CDC and its partners are continuing to address special issues related to the new algorithm, including more stringent requirements for handling of specimens; the absence of approved tests to use the algorithm with dried blood spots and oral fluids; the potential need for additional testing to determine HIV infection in vaccine recipients; this algorithm cannot be used with point of care rapid HIV tests.

CDC and HRSA issued a joint "Dear Colleague" letter in February 2013 to clarify questions and concerns raised by their grantees on HIV testing and linkage to care following a reactive rapid test result. The letter emphasized that no legislative requirement exists for a confirmed HIV diagnosis prior to linkage to RWP-funded medical care and no specific statutory or program requirement exists related to the use of the Western blot. The grantees were further informed that positive results from only one HIV antibody test should not serve as a barrier to linkage to care to RWP-funded clinics or other HIV care providers.

In addition to the specific advice CDC is requesting from CHAC, Dr. Branson also asked the members to consider the following issues during the discussion: the importance of detecting acute HIV infection; the need for an established infrastructure to implement the new sequence of laboratory tests; implications of the new algorithm on rapid HIV testing programs; and the availability of NATs to establish the diagnosis of acute HIV infection. He informed CHAC that CDC currently is developing program guidance for HIV testing in non-clinical settings.

CHAC discussed the following topics in the question/answer session with Dr. Branson on the draft recommendations and new algorithm for diagnostic laboratory testing of HIV infection.

- The current market for and adoption of fourth-generation HIV tests by laboratories, states and territories.
- The critical need to incorporate viral load testing into the HIV diagnosis to improve linkage to care.
- The need to educate and provide TA to clinicians on the types and thresholds of available viral load tests to ensure accurate interpretation of NAT results in clinical settings. Clinicians can order a viral load test as the NAT in the new algorithm, but only one qualitative RNA test is currently FDA-approved for diagnosis, so that laboratories cannot automatically perform viral load tests as part of the algorithm.
- Continued laboratory use of the Western blot algorithm.
- The need to develop a simplified set of recommendations, frequently asked questions or other types of practical guidance for non-traditional HIV testing sites and PCPs.
- The need to clearly communicate the implications of the new HIV testing algorithm to three distinct audiences: clinicians, laboratories and community testing programs.

CHAC advised CDC to publish the successful public health model in Massachusetts in which less costly phlebotomy specimens are submitted to laboratories for fourth-generation testing instead of conducting rapid HIV testing in some cases. Publication of the Massachusetts experience in the *MMWR* or another venue would be extremely helpful to other states.

CHAC also was in favor of engaging the CDC-funded PTCs and HRSA-funded AETCs to develop, adapt and widely disseminate communication tools, educational resources and curricula (e.g., a 1-hour presentation or a web-based case study) to educate care providers and the public on the new HIV diagnostic sequence. These tools and resources should emphasize the importance of using HIV test results as the entry point to linkage to care.

Dr. Steven Johnson volunteered to serve as the champion for drafting CHAC's resolution on CDC's draft recommendations and new algorithm for diagnostic laboratory testing of HIV infection.

### Update by the CHAC Data Workgroup

#### **Jennifer Kates, PhD, CHAC Member**

Vice President & Director, Global Health and HIV Policy  
Kaiser Family Foundation

Dr. Kates joined the meeting remotely and covered the following topics in her update on the workgroup's recent activities. CHAC unanimously approved the formation of the workgroup during the December 2012 meeting in response to key outcomes. HRSA presented preliminary

findings on RWP client-level data. CHAC discussed the importance of these data in assessing the impact of ACA on PLWH. CHAC emphasized the need for its ongoing interaction with CDC and HRSA on the use of MMP and other datasets to improve access to care, coverage and delivery of services to PLWH as the transition is made to an ACA environment.

The workgroup currently includes representation by CHAC, CDC and HRSA/HAB, but efforts are underway to also include staff from the HRSA Bureau of Primary Health Care. The workgroup anticipates that its future recommendations will be designed to build on and expand existing data analyses by CDC and HRSA to have a stronger focus on policy issues.

The workgroup will use presentations by CDC and HRSA during meetings and continue its ongoing dialogue with the federal agencies in between meetings to draft recommendations for CHAC's formal vote in the future. For example, the current CDC-focused meeting included an overview of MMP, while the next HRSA-focused meeting will include an update on RWP client-level data and other studies related to ACA. Dr. Kates noted that the workgroup is still in the early "information-gathering" phase and has no formal resolutions, recommendations or action items for CHAC's consideration at this time.

CHAC advised the workgroup to review the CDC and HRSA datasets with breakdowns by racial/ethnic minority groups. This approach will be useful in identifying emerging trends or new HIV infections and improving efforts to target interventions and limited resources. For example, African American MSM account for a considerable proportion of all new HIV infections in the United States.

### **Update by the CHAC Sexual Health Workgroup**

#### **John Douglas, Jr., MD**

Chief Medical Officer, National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention  
Centers for Disease Control and Prevention

Dr. Douglas covered the following topics in his update on the workgroup's recent activities. During the December 2012 meeting, CHAC unanimously approved a one-year extension for the workgroup to achieve two key goals: (1) implement a sexual health framework in the field and (2) develop strategies to disseminate sexual health information.

The workgroup has played an instrumental role in developing and providing input on recent and upcoming publications of sexual health papers. However, the workgroup primarily has been inactive over the past six months due to uncertainties regarding the ability of "recipient" agencies to actually implement and incorporate CHAC's advice and guidance into their existing priorities.

In an effort to fulfill its extended charge, the workgroup largely has focused on the feasibility of merging multiple prevention priorities into one “infectious disease” or “sexual health” topic in primary care. However, the workgroup acknowledges that these potential approaches are problematic due to the need to consider age, cultural sensitivity, population-based issues, and topics outside of CHAC’s purview (e.g., unintended pregnancies and sexual violence). The workgroup will report its final conclusions during the next CHAC meeting.

### **Update by the CHAC Viral Hepatitis Workgroup**

#### **Antigone Dempsey MEd, CHAC co-Chair**

Deputy Director, Knowledge, Transfer and Technical Assistance  
HIV/AIDS Lead, Altarum Institute

Ms. Dempsey covered the following topics in her update on the workgroup’s recent activities. CHAC unanimously approved the formation of the workgroup during the May 2012 meeting with a three-part charge. First, opportunities would be identified within CDC and HRSA to improve and coordinate prevention, screening, linkage to care, and treatment for persons with chronic HBV and HCV infection.

Second, the current state and adequacy of surveillance measures would be assessed for both acute and chronic hepatitis, core indicators and quality measures to (1) determine whether existing measures are adequate to evaluate gaps, barriers and progress in implementing CDC’s HCV screening recommendations for the 1945-1965 birth cohort and other elements of VHAP and (2) assess missed opportunities for earlier diagnosis to prevent morbidity and mortality. Third, the implications of ACA on VHAP would be evaluated.

The workgroup’s membership includes representation by CHAC, CDC, HRSA, HHS and multiple community partners. The workgroup has focused on three major policy issues in its most recent meetings: (1) renewal of the Action Plan for the Prevention, Care and Treatment of Viral Hepatitis, (2) young persons who inject drugs and are at risk for HCV infection, and (3) the potential impact of ACA on viral hepatitis.

In terms of the second policy issue, a new epidemic has emerged among young IDUs who have a 45% incidence of HCV. The HHS Office of HIV/AIDS Policy held a consultation with several agencies to discuss this topic. A number of workgroup members were in attendance as well. The meeting summary is available on the AIDS.gov website. The workgroup would propose recommendations on the three policy issues for CHAC’s formal vote during the business session.

**Chris Taylor**

Associate Director for Viral Hepatitis  
National Alliance of State and Territorial AIDS Directors

Mr. Taylor is one of the community partners that serve on the workgroup. He announced that VHAP is a comprehensive document to specify the roles and responsibilities of various federal agencies in achieving national goals for the prevention, care and treatment of viral hepatitis with limited resources. VHAP will end in 2013, but a request for information was released for the public to provide input on the next plan. The public comment period will close in early July 2013.

The workgroup is formulating recommendations for both HHS and non-HHS agencies to consider in using the existing infrastructure to prioritize activities that will have the greatest impact on the HCV epidemic over the next three years. In this effort, the workgroup will review feedback submitted by stakeholders during HHS's listening sessions and public comments submitted in writing.

**Update by the CHAC Ryan White Reauthorization Workgroup****Kathleen Clanon, MD, CHAC Member**

Director, Division of HIV Services  
Alameda County Medical Center

Dr. Clanon joined the meeting remotely and covered the following topics in her update on the workgroup's recent activities. CHAC unanimously approved the formation of the workgroup during the May 2012 meeting with a charge of developing recommendations on RWP reauthorization for CHAC's consideration and potential adoption. The workgroup's guidance would be designed to reflect evolving care needs in the context of ACA implementation.

The workgroup is closely coordinating with and will continue to provide guidance to HRSA on the following activities. Collaboration with RWP grantees should be continued to better understand and apply the "payer of last resort" provision in the shifting coverage landscape. Components of the RWP Medical Home Model should be better defined since HIV now has been added to the list of chronic diseases. The role of Planning Councils should be re-envisioned to monitor service gaps, service utilization and HIV-related disparities rather than funding allocations.

Administrative functions (e.g., planning and training RWP staff to work in a health reform environment) should be reconsidered in building a new system. For example, support for the role of RWP staff that assists PLWH should not be limited by administrative caps. The

workgroup will advise HRSA to take the lead on transforming RWP peer workers by changing the existing language and credentials for these workers to reflect a PCMH model.

Dr. Clanon reminded CHAC that the workgroup was formed in May 2012 with a one-year timeline to fulfill its charge. During the business session, she asked CHAC to make a decision on whether the workgroup should disband at this time, request a one-year extension, or merge with the new “Integration Workgroup” if formally approved.

Several members recalled that CHAC previously developed principles for a medical home specific to HIV care, including substance use and mental health services. CHAC advised the workgroup to review and update these principles based on changes in the evolution between the past medical home and the current PCMH model. Most notably, some clinics will not meet the criteria for medical home designation.

### CHAC Business Session

#### **Antigone Dempsey MEd, CHAC co-Chair**

Deputy Director, Knowledge, Transfer and Technical Assistance  
HIV/AIDS Lead, Altarum Institute

#### **Jeanne Marrazzo, MD, MPH, CHAC co-Chair**

Professor of Medicine, Harborview Medical Center  
University of Washington

For the benefit of the new members, Ms. Dempsey and Dr. Marrazzo explained that CHAC would not use the business session to “wordsmith” the proposed recommendations/resolutions due to time constraints. Instead, broad changes, additions or deletions should be suggested in order for CHAC to vote on the spirit, concept or intent of the proposed recommendation/resolution.

After the meeting, the proposed recommendations/resolutions would be revised based on CHAC’s input and circulated to the members for review and further comment before the co-Chairs drafted letters or position statements to the HHS Secretary, CDC Director and/or HRSA Administrator.

Ms. Dempsey and Dr. Marrazzo opened the business session and called for CHAC’s review, discussion and/or formal action on the following topics.

#### **Topic 1: Adoption of the Draft CHAC Meeting Minutes**

Dr. Marrazzo entertained a motion for CHAC to approve the previous meeting minutes. A motion was properly placed on the floor and seconded by Drs. Carlos del Rio and Steven Johnson, respectively, for CHAC to approve the previous meeting minutes.

**CHAC unanimously adopted the Draft December 11-12, 2012 Meeting Minutes with no changes or further discussion.**

**Topic 2: New "Integration Workgroup"**

**Champions: Kali Lindsey; Antigone Dempsey, MEd**

The following motion was properly placed on the floor and seconded by Mr. Kali Lindsey and Mr. Guillermo Chacon, respectively, for CHAC to establish a new "Integration Workgroup" with the following charge:

**Goals**

- Assess integration and transition strategies for HIV, viral hepatitis and STD prevention, care and treatment in the ACA environment.
- Issue recommendations and policy position statements to the HHS Secretary for consideration in an integrated ACA environment (both Medicaid and the Marketplace), Ryan White, and implementation of high-impact prevention initiatives.

**Objectives**

- Understand how to enhance the delivery of sexual health and substance use assessments, screening and referrals in primary care and other prime outpatient settings. Make policy recommendations based on these findings.
- Create policy recommendations that will help maintain access to comprehensive and high-quality care for persons with communicable diseases wherever their care is provided.

**Process**

- The workgroup will complete its work via conference call and consider strategies by topic area (e.g., integrating HIV, HCV and STD prevention and care) while looking across federal departments and funding streams to recommend approaches and interventions that can improve clinical operations and achieve desired population-based and individual-level health outcomes.
- With input from community, national, state and local stakeholders as well as federal representatives, the workgroup will seek to identify persistent barriers to service integration for HIV, viral hepatitis and STD prevention and care in an ACA environment. The workgroup will catalogue best practices and strategies, and work with federal representatives to identify and target opportunities to improve service and system delivery through ACA implementation.

**Structure**

- The new Integration Workgroup will be a standalone workgroup that will not replace any other group. The proposed membership is:
  - *Co-Chairs:* Kali Lindsey; Antigone Dempsey, MEd  
*Members:* Bruce Agins, MD, MPH; Virginia Caine, MD; Guillermo Chacon; Steven Johnson, MD. (Mr. Lindsey will serve as the liaison to the Ryan White Reauthorization Workgroup.)

**CHAC unanimously approved the recommendation.**

**Topic 3: Integration of Clinical Preventive Services in Primary Care Settings**  
**Champions: Sanjeev Arora, MD, FACP; Kathleen Clanon, MD; Dawn Fukuda, ScM**

The following motion was properly placed on the floor and seconded by Ms. Dawn Fukuda and Dr. Bruce Agins, respectively, for CHAC to formally adopt and submit the following resolution to the HHS Secretary. The purpose of the resolution is for the HHS Secretary to take concrete action steps in developing strategies to decrease barriers to HIV, STD and HCV care in primary care settings.

Recognizing that the provision of screening and care for persons with HIV, viral hepatitis and STDs is increasingly occurring in primary care settings, CHAC calls for a process to identify and define effective strategies for this to occur. This effort would include consideration of multiple strategies to increase the supply of care, leverage clinical expertise, and support effective team-based care models. CHAC requests the consideration of mechanisms to enhance the capacity of the primary care system to serve persons with viral hepatitis. These strategies include, but are not limited to, community health assessments (such as the use of surveillance and epidemiology to assess disease burden and populations at greatest risk at local levels) to help prioritize activities; assess and prioritize task shifting strategies, payment structures, ECHO® and other models for supporting wide availability to health care providers with the necessary expertise; and consideration of designating Ryan White-supported clinics to provide care for persons with HCV. With regard to HCV specifically, CHAC advises HRSA to engage HHS agencies to include this recommendation in the 2014 HHS Viral Hepatitis Action Plan.

**CHAC unanimously approved the resolution.**

**Topic 4: Electronic Medical Records**  
**Champion: Jeanne Marrasso, MD, MPH**

The following motion was properly placed on the floor and seconded by Drs. Jeanne Marrazzo and Carlos del Rio, respectively, for CHAC to formally adopt and submit the following resolution to the HHS Secretary with copies to the CDC Director and HRSA Administrator.

The HHS National Coordinator for Health Information Technology should, in collaboration with CDC and the public health community, develop and promulgate standards and certification criteria for EMRs that assure that providers using these systems have the capacity and flexibility to track key public health and clinical outcomes of interest to CHAC, including measures of care for HIV, viral hepatitis and STD. Such measures should include relevant Clinical Quality Measures, deemed critical to assess the quality of preventive care and endorsed by the National Quality Forum and other appropriate organizations. Ideally, public health entities should have the ability to monitor performance metrics among agreeable providers. Systems should allow and facilitate health care providers' ability to promptly and efficiently identify opportunities for performance improvement and intervention and track the implementation of those interventions among people living with or at risk for HIV, viral hepatitis, and STD.

Because this landscape is evolving so quickly, CHAC will track this issue closely in concert with colleagues at CDC and HRSA, and develop further recommendations as indicated.

**CHAC unanimously approved the resolution.**

**Topic 5: CDC/HRSA-Ryan White Funding**

**Champions:** Dawn Fukuda, ScM; Angelique Croasdale, MA; Jennifer Kates, PhD; Jeanne Marrazzo, MD, MPH

The following motion was properly placed on the floor and seconded by Ms. Dawn Fukuda and Dr. Jeanne Marrazzo, respectively, for CHAC to formally adopt and submit the following resolution to the CDC Director and HRSA Administrator. The purpose of the resolution is to emphasize the need to assess the impact of CDC and HRSA-Ryan White contributions on the HIV/AIDS response and the implications to the system of eliminating these resources.

In the context of the evolving healthcare system and national ACA implementation, CHAC recommends that HHS utilize existing analyses that have been accomplished through the Medical Monitoring Project and other studies to quantify the impact of significant reductions in CDC, HRSA-Ryan White and other discretionary funding for HIV, STD and HCV prevention and care, ideally at the level of local healthcare jurisdictions (city and state levels).

The recommended assessment must include projected impacts on the level of prevention, care and treatment activities delivered; the integrity and sustainability of the

HIV prevention and care infrastructure; and the anticipated effect on HIV health outcomes along the HIV Care Continuum.

The recommended assessment must take into consideration the limitations of these analyses to predict the specific extent to which prevention and care services that historically have been funded by CDC and HRSA can effectively be transferred to third-party reimbursement structures as well as the sufficiency of these payment mechanisms to sustain or improve the existing infrastructure and provider capabilities.

While a full understanding of cost shifting and the sufficiency of alternate payer sources will not be possible until ACA implementation is fully established, projections are essential to anticipate gaps that risk negative health outcomes (e.g., increased HIV incidence, HIV-related morbidity or mortality, and exacerbation of health disparities).

**CHAC unanimously approved the resolution.**

**Topic 6: CHAC/Presidential Advisory Council on HIV/AIDS (PACHA) Collaboration**  
**Champion: Antigone Dempsey, Med**

The following motion was properly placed on the floor and seconded by Ms. Antigone Dempsey and Mr. Guillermo Chacon, respectively, for the CHAC Ryan White Reauthorization Workgroup to establish a formal relationship with the PACHA “Expanding Access” Workgroup. Ms. Kaye Hayes, CHAC *ex-officio* member for HHS and PACHA Executive Director, will serve as the liaison between the two groups.

**CHAC unanimously approved the recommendation.**

**Topic 7: Draft Recommendations for the New HIV Diagnostic Laboratory Testing Algorithm**  
**Champion: Steven Johnson, MD**

The following motion was properly placed on the floor and seconded by Drs. Steven Johnson and Carlos del Rio, respectively, for CHAC to formally adopt and submit the following resolution to the CDC Director:

CHAC strongly endorses CDC’s draft recommendations on the revised HIV diagnostic laboratory testing algorithm. CHAC recommends education and technical assistance to laboratories, providers, and all other entities that are responsible for the delivery of HIV prevention and screening. Education and technical assistance should include strategies to (1) adopt the new algorithm and (2) provide test results as soon as possible to facilitate early diagnosis, prevention of transmission, and linkage to care.

**CHAC unanimously approved the resolution.**

**Topic 8: CHAC Viral Hepatitis Workgroup**  
**Champion: Antigone Dempsey, MEd**

The following motion was properly placed on the floor and seconded by Ms. Antigone Dempsey and Dr. Jeanne Marrazzo, respectively, for CHAC to formally adopt and submit the following resolution to the CDC Director and HRSA Administrator. The purpose of the resolution is to address young persons who inject drugs and those who are at risk for IDU or HCV infection.

CHAC recommends an increase in community-level education and messaging, intervention strategies on HCV risks, injection transmission risks, and HCV testing and linkage to care resources. These strategies specifically should target young IDUs and young persons who are at risk for IDU.

CHAC further recommends an assessment of CDC's infrastructure for HCV surveillance and data collection and application of these findings to make necessary improvements to better address epidemics in new populations.

CHAC advises CDC and HRSA to consider these recommendations as progress is made on the action steps for the 2014 HHS Viral Hepatitis Action Plan. CHAC's recommendations should be considered in the context of the online request for information.

**CHAC unanimously approved the resolution.**

**Topic 9: HCV Testing of the 1945-1965 Birth Cohort**  
**Champion: Carlos del Rio, MD**

The following motion was properly placed on the floor and seconded by Dr. Carlos del Rio and Mr. Kali Lindsey, respectively, for CHAC to formally adopt and submit the following resolution to the HHS Secretary.

CHAC encourages the Health and Human Services (HHS) Secretary to examine the HHS, Centers for Medicare and Medicaid Services (CMS) "Welcome to Medicare" physical examination and standard screening practices as an opportunity to respond to CDC's recommendations for one-time HCV testing of the 1945-1965 birth cohort. To support implementation of this recommendation, CHAC recommends that CMS integrate the HCV birth cohort screening recommendation in the "Welcome to Medicare" physical examine and/or during the Medicare annual preventive wellness examination.

**CHAC unanimously approved the resolution.**

## Topic 10: Future Agenda Items

CHAC proposed several topics to include on future meeting agendas.

- **HRSA (Dr. Laura Cheever):** Comprehensive overview of performance measures to answer the following questions:
  - What is the current status of the measures?
  - What is the meaning of individual measures?
  - Who is responsible for developing and approving the measures?
  - Do geographic variations exist in the use of the measures (e.g., regional versus state level)?
  - What is the role of the measures in CMS Meaningful Use criteria?
- **HRSA (Dr. Laura Cheever):** Results of the HRSA Workforce Study
- **HRSA (Dr. Laura Cheever):** Progress report on the care and treatment of patients co-infected with HIV/HCV in Ryan White-funded clinics. The update should describe challenges in HIV/HCV co-management, particularly in the changing care landscape and the introduction of new agents
- **HRSA:** Overview of the impact of the chronic disease model in an ACA environment on Ryan White-funded clinics. The update should describe challenges and opportunities in HIV management of the aging patient population, particularly in the context of chronic diseases and their outcomes.
- **HRSA:** Update on the role of Planning Councils and other planning bodies, including strategies for integrated planning efforts
- **HRSA:** Update on the role of ADAP in an ACA environment, including the availability of rebate resources to ensure continuity of care to PLWH
- **HRSA:** Status report on ACA implementation and the implications for HIV, HCV and STDs
- **CDC:** Overview of performance measures for HIV, viral hepatitis and STD testing
- **CDC/HRSA:** Update on the use of pre-exposure prophylaxis for HIV prevention in Ryan White Programs
- **CDC/HRSA (In-person meeting only):** Overview of workforce training activities to enhance and retain the knowledge, training and skills of providers in HIV care, new STD testing initiatives, viral hepatitis management and sexual health. The overview should include activities in these areas by HRSA-funded AETCs and CDC-funded PTCs.
- **CHAC:** Discussion on the increasing practice of substituting antiretroviral therapy with generic drugs. CHAC will need to periodically revisit this issue to ensure that substandard HIV care does not occur and persons continue to receive optimal first-line regimens as prescribed by their physicians. Health plans undoubtedly will attempt to cut costs as much as possible in an ACA environment.
- **Alliance of Chicago (Mr. Andrew Hamilton):** Overview of successful models of integrating Meaningful Use criteria, public health indicators and other performance measures into EMRs

## Topic 11: Action Items

CHAC reviewed the action items and other tasks that will need to be completed prior to the next meeting.

- Dr. Marrazzo will draft suggestions in response to Dr. Branson's specific request for CHAC's input on the draft recommendations and new algorithm for diagnostic laboratory testing of HIV infection. Dr. Marrazzo will circulate the preliminary feedback to CHAC for review and comment and then submit the revised input to Drs. Branson and Douglas as a formal CHAC communication.
- The CHAC co-Chairs and DFOs will update and distribute a dashboard that outlines the current status of CHAC's approved recommendations/resolutions. Beginning with the next meeting, the format will be modified for CHAC to review and discuss the dashboard while approving the minutes during the morning session.
- The Ryan White Reauthorization Workgroup will continue its activities with the following membership:  
*Chair:* Kathleen Clanon, MD  
*Members:* Tommy Chesbro; Angelique Croasdale, MA; Dawn Fukuda, ScM; Steven Johnson, MD. (Dr. Clanon will serve as the liaison to the new Integration Workgroup.)
- **The next meeting will be held on November 13-14, 2013 and will be piloted as CHAC's first "virtual" meeting.** The co-Chairs, DFOs and Committee Management Specialists will consider CHAC's suggestions outlined below in planning and preparing for the pilot virtual meeting:
  - Review best practices, lessons learned and successes of other Federal Advisory Committees that currently convene their meetings by webinar.
  - Identify creative approaches to ensure that the full CHAC membership remains engaged, focused and productive throughout the meeting (e.g., a 2-hour morning session and a 2-hour afternoon session on days 1 and 2).
  - Determine options to continue to convene "in-person" meetings to the extent possible. For example, CDC staff and CHAC members who are closer to Atlanta could attend the webinar at the CDC campus. HRSA staff and CHAC members who are closer to the DC area could attend the webinar at the HRSA campus. A group dynamic would improve communications and discussions among the CHAC membership, CDC/HRSA staff and guest presenters.
  - Identify CHAC members whose institutions have the resources to continue to support travel to in-person meetings. Alternatively, select dates for future CHAC meetings that coincide with other events in Atlanta or the DC area.
  - Administer a survey to determine the capabilities of CHAC members to attend virtual meetings. For example, some CHAC members who are state employees are

prohibited from using web cameras or other video equipment on their individual work computers.

- Establish a set of ground rules. For example, chat rooms are distracting, are not particularly useful, and should not be permitted during CHAC webinars.
- Develop a rigorous process and well-defined protocols to handle the potential increase in the number of persons who sign up for public comment during virtual CHAC meetings.
- Identify a mechanism for CHAC members to interact with presenters offline, particularly if questions need to be answered to draft recommendations/resolutions.
- Develop future agendas to be appropriate and feasible for a 4-hour meeting on days 1 and 2.
- Consider increasing the number of annual CHAC meetings in the future if the pilot virtual meeting is successful.

### **Closing Session**

Ms. Dempsey and Dr. Marrazzo thanked the CHAC members for overcoming numerous travel and logistical barriers to attend the meeting. The participants joined the co-Chairs in applauding Dr. Douglas, Ms. Margie Scott-Cseh, the CDC Committee Management Specialist, and other CDC staff for organizing and planning the CHAC meeting.

Drs. Cheever and Douglas thanked the CHAC members for providing CDC and HRSA with sound advice and concrete recommendations over the course of the meeting. They noted that CDC and HRSA continue to value and utilize CHAC's guidance in informing their future directions in improving HIV, viral hepatitis and STD prevention and treatment for the nation. The participants joined Drs. Cheever and Douglas in applauding Ms. Dempsey and Dr. Marrazzo for their outstanding roles as co-Chairs of the meeting.

With no further discussion or business brought before CHAC, Ms. Dempsey adjourned the meeting at 12:34 p.m. on June 19, 2013.

I hereby certify that to the best of my knowledge, the foregoing Minutes of the proceedings are accurate and complete.

\_\_\_\_\_  
Date

\_\_\_\_\_  
Antigone Dempsey, MEd, Co-Chair  
CDC/HRSA Advisory Committee on HIV,  
Viral Hepatitis and STD Prevention and  
Treatment

\_\_\_\_\_  
Date

\_\_\_\_\_  
Jeanne Marrazzo, MD, MPH, Co-Chair  
CDC/HRSA Advisory Committee on HIV,  
Viral Hepatitis and STD Prevention and  
Treatment



## Participants' Directory

### CHAC Members Present

Ms. Antigone Dempsey, co-Chair  
Dr. Jeanne Marrasso, co-Chair  
Dr. Sanjeev Arora  
Dr. Virginia Caine  
Mr. Guillermo Chacon  
Mr. Tommy Chesbro  
Dr. Kathleen Clanon  
Ms. Angelique Croasdale  
Dr. Carlos del Rio  
Ms. Dawn Fukuda  
Dr. Perry Halkitis  
Dr. Marjorie Hill  
Dr. Steven Johnson  
Dr. Jennifer Kates  
Mr. Kali Lindsey

### CHAC Members Absent

Dr. Marjorie Hill  
Ms. Regan Hofmann  
Dr. Britt Rios-Ellis

### CHAC Ex-Officio Members Present

Dr. Pradip Akolkar  
Food and Drug Administration

Dr. William Grace  
National Institutes of Health

Ms. Kaye Hayes  
Office of HIV/AIDS and Infectious Disease  
Policy, U.S. Department of Health and  
Human Services

Dr. Mabry-Hernandez  
Agency for Healthcare Research and  
Quality

Ms. Lisa Neel  
Indian Health Service

Dr. Richard Wild (Alternate)  
Centers for Medicare and Medicaid  
Services

### CHAC Ex-Officio Member/ Liaison Representative Absent

Mr. Douglas Brooks  
Presidential Advisory Council on HIV/AIDS

Dr. Steve Cha  
Centers for Medicare and Medicaid  
Services

### CHAC Designated Federal Officers

Dr. Laura Cheever  
(Acting) HRSA/HAB Associate Administrator

Dr. John Douglas, Jr.  
CDC/NCHHSTP Chief Medical Officer

## Federal Agency Representatives

Mr. Gustavo Aquino  
Dr. Stuart Berman  
Dr. Gail Bolan  
Dr. Bernard Branson  
Dr. Chris Cagle  
Ms. Corinna Dan  
Dr. Hazel Dean  
Ms. Teresa Durden  
Mr. Norm Fikes  
Ms. Shelley Gordon  
Dr. Seiji Hayashi  
Mr. Michael Hendry  
Dr. Matthew Hogben  
Dr. Kathleen Irwin  
Ms. Priya Jakhmola  
Dr. Rima Khabbaz  
Ms. Karen Kroeger  
Ms. Virginia Lipke  
Ms. Claire Loe  
Ms. Jennifer Ludorie  
Ms. Kristen Mangold  
Ms. June Mayfield  
Dr. Jonathan Mermin  
Dr. Ninad Mishra  
Dr. John Moore  
Ms. Amy Pulver  
Ms. Laurie Reid  
Mr. Dan Riedford  
Ms. Susan Robinson  
Dr. Raul Romaguera  
Ms. Margie Scott-Cseh  
Dr. Salaam Semaan  
Dr. Jacek Skarbinski  
Ms. Amrita Tailor  
Ms. Abigail Viall  
Dr. John Ward  
Ms. Lynn Wegman  
Mr. Terry Wheeler  
Mr. Erik Williams  
Dr. Richard Wolitski  
Dr. Pascale Wortley

## Members of the Public

Dr. Wendy Armstrong  
Emory University

Ms. Rosemary Donnelly  
Emory University

Mr. William Garrett  
New York State Department of Health AIDS  
Institute

Dr. Daniel Miller  
Hudson River HealthCare

Dr. Hogai Nassery  
Grady Health System

Ms. Stephanie Arnold Pang  
National Coalition of STD Directors

Mr. Carl Schmid  
The AIDS Institute

Mr. Michael Shankle  
HealthHIV

Dr. David Stevens  
National Association of Community Health  
Centers

Mr. Chris Taylor  
National Alliance of State and Territorial  
AIDS Directors

Ms. Cathalene Teahan  
Georgia AIDS Coalition

Mr. Daniel Tietz  
ACRIA

Ms. Marissa Tonelli  
HealthHIV

Ms. Carole Treston  
Association of Nurses in AIDS Care



## Glossary of Acronyms

ACA	Patient Protection and Affordable Care Act
ACOs	Accountable Care Organizations
ADAP	AIDS Drug Assistance Program
AETCs	AIDS Education and Training Centers
ART	Antiretroviral Therapy
CAB	Community Advisory Board
CBO	Community-Based Organization
CCO	(Oregon) Coordinated Care Organization
CDC	Centers for Disease Control and Prevention
CHAC	CDC/HRSA Advisory Committee on HIV, Viral Hepatitis and STD Prevention and Treatment
CHCs	Community Health Centers
CMMI	Center for Medicare and Medicaid Innovation
CMS	Centers for Medicare and Medicaid Services
CoAg	Cooperative Agreement
CSBS	Case Surveillance-Based Sampling
DASH	Division of Adolescent and School Health
DFOs	Designated Federal Officials
DHAP	Division of HIV/AIDS Prevention
DIS	Disease Investigation Service
DSTD	Division of STD Prevention
DVH	Division of Viral Hepatitis
ED	Emergency Department
EIA	Enzyme Immunoassay
EMRs	Electronic Medical Records
FDA	Food and Drug Administration
FOA	Funding Opportunity Announcement
FQHCs	Federally Qualified Health Centers
GISP	Gonococcal Isolate Surveillance Project
HAB	HIV/AIDS Bureau

HBV	Hepatitis B Virus
HCV	Hepatitis C Virus
HHS	U.S. Department of Health and Human Services
HIT	Health Information Technology
HPV	Human Papillomavirus
HRHCare	Hudson River HealthCare
HRSA	Health Resources and Services Administration
IDU; IDUs	Injection Drug Use; Injection Drug Users
IgG	Immunoglobulin G
IgM	Immunoglobulin M
IOM	Institute of Medicine
LGBT	Lesbian/Gay/Bisexual/Transgender
MMP	Medical Monitoring Project
<i>MMWR</i>	<i>Morbidity and Mortality Weekly Report</i>
MRAs	Medical Record Abstractions
MSM	Men Who Have Sex With Men
NACHC	National Association of Community Health Centers
NATs	Nucleic Acid Tests
NCHHSTP	National Center for HIV/AIDS, Viral Hepatitis, STD and TB Prevention
NCQA	National Committee for Quality Assurance
NHAS	National HIV/AIDS Strategy
NIH	National Institutes of Health
NQC	National Quality Center
NQF	National Quality Forum
OAR	Office of Antimicrobial Resistance
ONAP	Office of National AIDS Policy
PAB	Provider Advisory Board
PACHA	Presidential Advisory Council on HIV/AIDS
PCMH	Patient-Centered Medical Home
PCPs	Primary Care Providers
PEPFAR	President's Emergency Plan for AIDS Relief
PLWH	Persons Living with HIV
PPHF	Prevention and Public Health Fund
Project ECHO®	Extension for Community Healthcare Outcomes
PTC	Prevention Training Center
QI	Quality Improvement
RWP	Ryan White HIV/AIDS Program
SAMHSA	Substance Abuse and Mental Health Service Administration
SPNS	Special Projects of National Significance

TA	Technical Assistance
TILT-HEPC	Trainees Identifying and Linking to Treatment for Hepatitis C
UDS	Uniform Data System
UNM	University of New Mexico
USPSTF	U.S. Preventive Services Task Force
VHAP	Viral Hepatitis Action Plan